INTRODUCTION
It has been estimated that about 5% of the population suffer from a chronic skin, hair or nail condition; it is also estimated that over half of individuals over 65 years of age suffer from skin conditions such as seborrheic dermatitis, fungal infections and neoplastic growths. The skin is a remarkable organ, subjected to the extremes of the external environment and altered by the internal environment (the physiological processes occurring within the body), but responding with amazing resiliency.

THE SKIN
The skin is the largest organ in the body, averaging about 1 to 2 mm in thickness with the thickest skin on the palms and soles and the thinnest on the eyelids and scrotum. The skin is the envelope that wraps our bodies, keeps all the pieces together and serves numerous functions. It may be light or dark, smooth or wrinkled, but it helps define how we appear to others. This body covering, the skin is composed of the epidermis, dermis and the hypodermis.

Epidermis
The epidermis (0.075 to 0.15 mm thick) is composed mostly of compact, avascular stratified squamous epithelial cells. There are actually five layers to the epidermis (from the innermost to the exterior); the stratum germinativum, stratum spinosum, stratum granulosum, stratum corneum and the stratum lucidum. The lowest layer, the basal cell layer (stratum germinativum) is where new cells (keratinocytes) divide and move upward. The keratinocytes change from living cells to dead, thick-walled, flat, non-nucleated cells containing keratin as they move towards the skin surface. This layer is especially important in laying down new granulation tissue in conditions such as wounds, ulcers, etc. The next layer, the stratum spinosum contains keratinocytes, melanocytes and melanin granules, important for skin pigmentation. Changes in this region can alter skin coloring. Next, the stratum granulosum, containing several thicknesses of flattened polygonal cells, are rich in keratohyalin. The stratum lucidum, a translucent, thin area, (in the palms and soles) is a narrow band of flattened, closely packed cells. The surface layer, the stratum corneum, is composed of flat, scaly, dead (ker-
The stratum corneum cells are constantly being shed (desquamated) and are replaced by new cells generated by the mitotic process deeper down in the basal cell layer. Actually, the newer cells push the older cells closer to the surface and the cells become flattened, lose water, and are compressed as they move towards the surface. From basal cell formation to desquamation, the complete cycle, ranges from 28 to 45 days. The stratum corneum is about 15-20 cells thick; therefore, approximately 0.5 to 1 cell layer per day is sloughed off the body.

The stratum corneum, where most inflamations and disorders occur, maintains its flexibility because of its water content which is normally between 10 and 20%. This flexibility is influenced by humidity, temperature, surfactants, and physical or chemical trauma. The keratin can actually absorb several times its weight in water and retain it to maintain the flexibility and integrity. Water is important to the skin! Oleaginous vehicles are occlusive and aid in retaining the moisture in the skin. The stratum corneum is primarily lipophilic.

Dermis

The dermis (about 1 to 4 mm thick), or basement membrane separates the epidermis from the lower fatty layers and actually physically supports the epidermis. The dermis is composed mainly of collagen and elastin embedded in a mucopolysaccharide substance containing fibroblasts and mast cells. The dermis also contains a network of nerves, lymphatic and blood vessels, supplying hair follicles, sebaceous glands and sweat glands. It is this layer where the cutaneous sensations occur, for example, itching from the upper region, stinging from the middle region and pain in the region closest to the subcutaneous fat. The dermis contains the papillary and reticular layers. The former is rich in blood vessels and appears to aid in bringing nutrients to the avascular epidermis. The lower portion, the papillae, contains coarser tissue that connects the dermis with the hypodermis. Altered pain perception can occur when this layer is damaged, or even destroyed.

Hypodermis

The subcutaneous tissue, called the hypodermis is composed of loose connective tissue and adipose tissue. This layer aids in thermal control, holds nutrients and provides cushioning and/or padding. Burns extending into this area require close monitoring of the patient, depending upon the extent of involvement.

PURPOSE OF THE SKIN

The skin, the largest organ in the body, is the protective barrier between the body and the environment. The skin works to protect the body from chemicals and pathogenic organisms; its functions are dependent upon, and in association with, age, immunologic status, underlying disease states, use of oral/topical medications and the preservation of an intact stratum corneum.

In addition to protection, the skin also serves for temperature control, pigment development, water regulation/moisture loss and even vitamin synthesis. The skin can be challenged by wounds, burns, chafing, drying, internal physiological disorders, chemicals and bacteria, resulting in alterations and may involve the different skin layers. Commonly encountered dermatologic disorders include general classes of dermatitis and dermatoses. Specifically, allergic skin diseases include urticaria, atopic dermatitis (eczema), allergic contact dermatitis and photoallergic reactions. Others include insect bites/stings, acne, burns (including sunburn), minor wounds, skin infections, cancer, skin ulcers, hyperpigmentation, photoaging, lice infestation and even hair loss. Only a few, however, will be discussed here.

DEFINITIONS OF SKIN PROBLEMS

Dermatitis is used as a term to describe a number of conditions that are inflammatory and are generally characterized by erythema. The term literally means an inflammation of the skin. Dermatitis can be characterized by various skin appearances, such as a macula, wheal, subcorneal blister, intradermal blister, subepidermal blister, pustule, papule, rhagades, ulcer, squama, keratosis, scab (crusta), scar (cicatrix) and mucous membrane. Treatment of dermatitis can include anti-inflammatory agents, antibiotics, antifungals, corticosteroids, anesthetics and others.

Dermatosis is a nonspecific term used for any cutaneous abnormality or eruption. It includes many disorders and literally means, a disorder of the skin. Treatment depends upon the specific problem and the portion of the skin involved.

Eczema is a generic term for inflammatory conditions of the skin, particularly with vesiculation in the acute stage, typically erythematous, edematous, papular and crusting; followed by lichenification and scaling and occasionally by duskiness of the erythema and, infrequently, hyperpigmentation; often accompanied by sensations of itching and burning; the vesicles form by intraepidermal spongiosis. Eczema is treated by anti-inflammatory agents, antibiotics, antifungals, corticosteroids, anesthetics and other agents.

DISEASES OF THE SKIN AND THEIR TREATMENT

Acne vulgaris is characterized by comedones and other lesions, including scars and occurs throughout adolescence. Acne affects all skin layers even into the subcutaneous areas. The treatment objective is to clear the lesions, prevent scarring and minimize psychological distress. Acne is often treated by drying agents, proliferative agents, antibiotics, anti-inflammatory agents and others. A sample formulation often used is as follows;

Rx - Nicotinamide 4% Acne Gel
Nicotinamide 4 g
Carbomer 934 1 g
Methylparaben 50 mg
Propylparaben 10 mg
Triethanolamine qs
Purified water qs 100 mL

Accurately measure each ingredient. Dissolve the nicotinamide, methylparaben and propylparaben in about 95 mL of purified water. Disperse the carbomer 934 in the solution slowly so as to not form lumps. Add sufficient purified water to make 100 mL. Add triethanolamine dropwise to the desired viscosity. Package and label.

Psoriasis
Psoriasis is a chronic disease characterized by epidermal hyperplasia and a greatly accelerated rate of epidermal turnover. It was discussed in a special Secundum Artem (Volume 9, Number 4- Compounding for Patients with Psoriasis). This can be found online at www.paddocklabs.com.

Skin cancers
Skin cancer rates appear to be increasing but can be treated if caught early. An easy-to-apply sample formulation that has been used for treating certain small skin cancers is the following.

Rx - Fluorouracil 5% Medication Stick
Fluorouracil 5 g
Polybase 95 g

Accurately measure each ingredient. Melt the Polybase using low heat to about 60-65°C. Incorporate the fluorouracil, cool, and package into medication stick containers.

Skin ulcers
Skin ulcers may occur anywhere over the body but especially where the skin is subjected to constant rubbing or irritation. Decubitus ulcers in hospice patients and those confined to a bed are all too common. If malodorous, metronidazole topical solutions can be used, as follows;

Rx - Metronidazole 1% Topical Solution
Metronidazole 1 g
Hydrochloric acid 10% solution 1.5 mL
Propylene glycol 10 mL
Methylparaben 100 mg
Propylparaben 50 mg
Purified water qs 100 mL

Accurately weigh/measure each ingredient. Add the metronidazole to about 50 mL of purified water, followed by the hydrochloric acid 10% solution. Mix the parabens with the propylene glycol and add to the metronidazole solution. Add sufficient purified water to volume and mix well.

The following preparation has been effective in many cases to increase granulation from the lower tissues and enable the ulcer to fill in and heal, while making the patient much more comfortable.

Rx - Ketoprofen 2%, Lidocaine 2%, Phenytoin 2% and Misoprostol 0.0024% in Dermabase
Ketoprofen 2 g
Lidocaine HCl 2 g
Phenytoin 2 g
Misoprostol 2.5 mg
Dermabase qs 100 g

Accurately weigh/measure each ingredient. Mix the ketoprofen, lidocaine HCl, phenytoin and misoprostol with a small quantity of propylene glycol to form a paste. Geometrically, add sufficient Dermabase to 100 g and thoroughly mix.

Lice/Scabies
Lice/scabies is usually treated by scabicides and even insecticides. It is really a problem during the school terms when young children go back to school and tend to spread the lice. It has been occurring almost at epidemic levels in recent years and some of the routine commercial products are not effective. The following preparation, has been used quite effectively.

Rx - Malathion 0.5% Lotion for Head Lice
Malathion 500 mg
Isopropyl alcohol 70% 68 mL
Lavender oil 30 drops
Bay and/or pine oil 3 drops
Ethyl alcohol 95% qs 100 mL

Caution: Due to fumes, this should be prepared in a well-ventilated area or under an exhaust hood. The compounder should wear disposable gloves to prevent retention of odor on the hands. Accurately weigh/measure each ingredient. Disperse the malathion in the isopropyl alcohol; add fragrances and bring to volume with ethyl alcohol and mix well.

Insect Bites/Poison Ivy
Spring and summer bring a great increase in the incidence of insect bites and stings, as well as exposure to poison ivy, sumac and oak. Preparations used in treating these disorders often incorporate anesthetics in either sprays, creams or gel forms.

Rx - Lidocaine 2% Anesthetic Gel
Lidocaine 2 g
Carbomer 934 2 g
Ethanol 95% 90 mL
Triethanolamine qs
Purified water qs 100 mL

Accurately weigh/measure each ingredient. Dissolve the lidocaine in the ethanol. Disperse the carbomer 934 in the lidocaine:ethanol solution. Add the purified water and mix well. Add a few drops of triethanolamine to thicken the gel. Package and label.

Other preparations are more complex and incorporate anti-inflammatory/corticosteroids, antihistamines, and other antipruritics in various dosage forms, such as the following gel.
Rx - Insect Bite/Sunburn Gel
Hydrocortisone 1 g
Pramoxine HCl 1 g
Diphenhydramine HCl 2 g
Menthol 300 mg
Camphor 300 mg
Benzyl alcohol 1.6 mL
Hydroxypropyl cellulose 2 g
Propylene glycol 10 mL
Alcohol 70% 60 mL
Purified water qs 100 mL
Accurately measure each ingredient. Mix the alcohol with about 20 mL of purified water. Add the hydrocortisone, pramoxine HCl, diphenhydramine HCl, menthol, camphor and benzyl alcohol and mix well. Mix the hydroxypropyl cellulose with the propylene glycol and add to the drug solution. Add sufficient purified water to volume, package and label.

Hyperpigmentation
Hyperpigmentation can be related to the activity occurring in the region of the stratum spinosum, resulting in several different pigmentation disorders. Hyperpigmentation can be treated with bleaching agents, such as hydroquinone, generally applied two to three times daily. A sample preparation that has been used is as follows;

Rx - Bleaching Cream
Retinoic acid 100 mg
Triamcinolone 100 mg
Hydroquinone 4 g
Butylated hydroxytoluene 400 mg
Castor oil 4.5 g
Vitamin E acetate liquid (1 IU/mg) 1.75 g
Polysorbate 80 1 g
Propylene glycol 10 mL
Sodium ascorbate 3 g
Citric acid 1 g
Dermabase qs 100 g
Accurately weigh/measure each ingredient. Triturate the retinoic acid and triamcinolone with a small quantity of the propylene glycol. Add the hydroquinone powder and mix well. Incorporate the sodium ascorbate and citric acid. Add the butylated hydroxytoluene, polysorbate 80, castor oil and vitamin E acetate and mix well. Incorporate into the emulsion base and mix until smooth and homogenous. Note: Use mixing techniques that minimize incorporation of air into the product. This preparation is more stable when packaged to minimize contact with air, such as in a large syringe.

Fungal Infections
Fungal infections (mycoses) can be either superficial or deep infections and can involve many different microorganisms. When the nails are involved, therapy may last from 6 months to one year; treatment of the skin is usually shorter in duration. A sample preparation for treating fungal infections of the nail is as follows;

Rx - Fluconazole in Dimethyl Sulfoxide (DMSO)
Fluconazole 2 g
Dimethyl sulfoxide qs 100 mL
Accurately weigh the fluconazole. Dissolve the fluconazole in the DMSO or mix the finely powdered tablets with the DMSO. If the tablets were used, filter the preparation after the fluconazole has gone into solution. Package in a bottle with a glass rod applicator.

Wounds
A wound is trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity. There are many types of wounds and many involve the skin, either superficially, dermally or subcutaneously. Treatment is dependent upon the cause, location and potential for infection and further injury. A sample formula for abraded skin is the following;

Rx - Wound Care Mixture
Phenol 200 mg
Zinc oxide 12 g
70% Ethanol
Calcium hydroxide solution aa qs 100 mL
Accurately weigh/measure each ingredient. Prepare 100 mL of the vehicle using equal parts of 70% ethanol and calcium hydroxide solution (lime water). Dissolve the phenol in about 75 mL of this vehicle. Sprinkle the zinc oxide powder on the phenol-vehicle mixture. Add additional vehicle to volume and mix well. Package and label.

FORMULATING DERMATOLOGICALS
Dermatologicals have three primary functions. They are to provide for skin hydration (emollient effect), to protect injured areas from the environment and permit rejuvenation of the skin, and (3) to provide a means of convening a medication to the skin for a specific effect, either locally or systemically.

Formulating dermatologicals requires consideration of the flux of the drug into or across the skin, retention of the dosage form on the skin's surface, the reservoir capacity of the dosage form and the elegance/acceptability of the dosage form. When the water content of the skin drops less than about 10%, chapping occurs and the stratum corneum becomes brittle and will easily crack. This results in irritants and bacteria being able to penetrate more easily, causing dermatitis and other skin conditions. The cell cycle of 28 to 45 days must be considered because some topically applied medications may not be effective until the complete cycle ends.

Commonly prepared dermatologicals include ointments, creams, lotions, pastes, gels and sticks. Ointments are semisolid preparations that will either soften or melt at body temperature and are generally used on dry, scaly lesions, as their emollient properties will aid in rehydrating the skin. They will also adhere for an extended period of time. Ointments are general-
ly used for topical/local application of drugs, mostly for local or topical effects.

Creams are opaque, soft solids or thick liquids intended for external application, consisting of medications dissolved or suspended in vanishing cream or emulsion bases; either oil-in-water or water-in-oil. Creams are usually applied to moist, weeping lesions and have somewhat of a “drying” effect, because the exuded fluids will be miscible with the emulsion vehicles. Creams can be formulated to aid in drug penetration into or through the skin.

Lotions are fluid emulsions or suspensions for external application, including both suspension and oil-in-water dosage forms. They are generally applied to intertriginous areas where rubbing occurs, as between fingers, thighs, under the arms, etc, as they have a lubricating effect. Suspension lotions, or patting lotions, are applied by application/patting but are not rubbed in; the suspended particles may cause slight damage to the sensitive skin.

Pastes are thick, stiff ointments that ordinarily do not flow at body temperature and serve as protective coatings over areas to which they are applied; they usually contain at least 20% solids.

Gels are semirigid systems in which the movement of the dispersing medium is restricted by an interlacing, three-dimensional network of particles or solvated macromolecules of the dispersed phase. After application, the liquid evaporates leaving the drug entrapped in a thin film of the gel-forming matrix physically covering the skin.

Sticks are a convenient form for administering topical medications and are solid dosage forms that melt at body temperature, releasing their medication or providing a protective barrier.

Other Considerations

If the drug is not incorporated as a solution into the dosage form, a very fine particle size is advantageous. Commination of all incorporated powders is important to minimize any damage to the skin upon application.

If the skin is dry, an oleaginous ointment base (petrolatum) is recommended as a hydrated stratum corneum generally enhances drug diffusion and absorption. The cells of a well-hydrated stratum corneum are swollen, loosening the normally, tight, densely packed configuration. The hydration of the stratum corneum is increased by occlusion. Also, the additional water composition increases the absorption rate of ionized, hydrophilic drugs.

Various bases affect the hydration of the skin; for example ointments tend to enhance hydration and creams tend to be more drying over time. This is because as the area is washed or rinsed in water, the emulsifier in the cream/lotion-emulsion also can emulsify the natural body oils with their ultimate removal from the skin. The skin is then robbed of its protective natural oils, allowing water to evaporate and the skin to dry out.

Some general procedures for preparing dermatological dosage forms include the following.

1. Comminute insoluble materials to a very fine state of subdivision.
2. Levigating agents used for comminution must be compatible with the active ingredient and the vehicle.
3. Geometric dilution will enhance uniformity of distribution of the active ingredient in the vehicle.
4. Solvents with low vapor pressures, such as water, glycerin and propylene glycol should be used in place of alcohol and higher vapor pressure solvents (which will evaporate and may lead to crystallization of the drug).
5. When fusion is used and volatile substances are to be incorporated, allow the melt to cool before adding the volatile ingredients.
6. Aqueous systems should be heated for as short a time as possible to minimize water loss due to evaporation.
7. If a preparation is too stiff, decrease the proportion of waxy components and if an emulsion, increase the proportion of water.
8. For maximum preparation stability, try to keep the product anhydrous.
9. Mixing two creams/ointments can be easily accomplished in a plastic bag; this also simplifies cleanup. The preparation can easily be placed in a tube/syringe by snipping the corner off the plastic bag and squeezing the contents into the package.
10. Kitchen mixers can be used when preparing large quantities of semisolids.
11. Geometric dilution techniques will actually speed up the preparation time.
12. For ingredients that build up electrostatic charges, a few drops of a levigating agent works well.
13. Humectants can be added to cream/lotion formulations to increase their hydrating properties.
14. When preparing bases using fusion, melt the ingredient with the highest melting point first, followed by those with decreasing melting points.

REFERENCES


NOTES
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INTRODUCTION: THE GRAYING OF AMERICA
For the first time in our history, medical advances in the 20th century have made it possible that more than 10% of some national populations are over the age of 65. This has been referred to as the “graying of America” in the United States and has stimulated interest in the consequences of aging and the care of the elderly. The branch of medicine dealing with medical problems and care of the elderly is called “geriatrics”. The more broadly based scientific discipline that deals with all aspects of aging (social, biological, psychological, etc.) is called “gerontology”.

We commonly, or intuitively, know that each day animals are born, grow, mature, then begin to lose some of their capabilities to function “normally”, then finally they die. This chronology and the onset of aging is specific to each species; for example, the dog is old at about 12 years, rodents at 2 or 3 years, a horse at 15 to 20 years and a human at about 60 to 90. It appears that there is an organizational plan within each species. An interesting phenomena related to aging is the Hayflick phenomenon, named after the American biologist who first described it. It is related to factors within the cell of a species that determine its capacity to multiply, the exhaustion of that capacity and its relation to life span. For example, cells removed from an organism and allowed to grow in tissue culture will divide only a certain number of times and then die. In humans, there are about 50 divisions, about 25 in the chicken and about 14 to 28 in the mouse; but the Galapagos tortoise undergoes 90 to 125 doublings. If the normal explanted human cells have undergone about 40 divisions and then frozen and thawed, they will only undergo about 10 additional divisions; again related back to the number unique to the species.

The loss of capabilities of an individual during aging is progressive, irreversible and universal for all members of a specific species and is termed “aging”. From the outward appearance, it is very evident in humans as a decline in height, muscle shrinkage, thinning and graying of hair and wrinkling of skin. Internally, it is more significant as there is a progressive loss of cells in the brain, kidneys and other vital organs. There is less competence in these cells and tissues and this is reflected in functional declines by the individual. It appears that nerve cells from the brain to

GOALS AND OBJECTIVES
Goal: To provide supportive information to assist pharmacists in more effectively counseling geriatric patients and in advocating the rational treatment of arthritis.
Objectives: After reading and studying this article, the participant should be able to:
1. discuss the characteristics of the aging patient.
2. define the various types of arthritis.
3. describe the various approaches to treating the different types of arthritis.
4. consult with healthcare professionals in the management of arthritis, and the compounding of patient-specific medications.
the spinal cord diminish and those that remain conduct impulses at a slower rate so that reaction time is slowed; also, memory shows a decline.

There is much biological variability in the aging process; some individuals appear “old” at age 50 and others are quite active even at age 80 or 90. Generally, the longer-lived individuals show a later onset of the aging process and a slower progression in the rate of aging than “normal”. There also appears to be a genetic factor involved as long life seems to run in families. Disuse of bodily organ systems appears to accelerate their deterioration. This is quite obvious with muscle and bone but it also is true of memory and thinking. Consequently, it is important to exercise both the body and the mind throughout life and not settle into a “passive” lifestyle. Another interesting phenomenon is that nonsmoking can increase one’s life expectancy by about four years.

**PHYSIOLOGICAL CHANGES IN THE ELDERLY**

As one ages, there is a multitude of changes that occur in almost every system in the body. These changes include increased adipose tissue of 14-30% by age 70, decreased lean body weight, decreased total body water and plasma volume and decreased thickness of the skin. Also included are the loss of teeth, decreased salivation, decreased GI motility, neurological changes including decreased neurons, brain weight and volume, decreased cognitive skills and increased reaction to positive or negative stimuli. Decreased estrogen can lead to osteoporosis, decreased glucose tolerance and atrophy of the thyroid gland also occurs. Hepatic changes include decreased liver size, decreased hepatic blood flow and decreased albumin with serious disease or poor nutrition. In the kidney, there is a decrease in the glomeruli by 30-40% by age 80, decreased creatinine clearance without a decrease in serum creatinine, decreased renal blood flow, decreased renin and a decreased concentrating ability. There can also be visual and auditory problems, decreased respiratory function, decreased active transport, decreased first-pass metabolism and increased gastric pH.

One problem with drug therapy in the elderly is that their pharmacokinetics and pharmacodynamics are different than those in the median-age adult. Due to the generally slower rate of drug metabolism, inappropriate drug therapy in the elderly can cause symptoms that may be misinterpreted as disease symptoms, especially dizziness and falling. Inappropriate therapy can also cause impaired quality of life, hospitalization and even death. The general tendency is to overmedicate the elderly.

**DISEASES/DISORDERS AFFECTING THE ELDERLY**

Diseases affecting the elderly include hearing loss, atherosclerosis, Alzheimer’s, polymyalgia rheumatica, fibromyalgia, giant cell arteritis, crystal arthropathies (such as gout), falls, fractures, osteoporosis, insomnia, depression, dementia, urinary incontinence, benign prostate hypertrophy, urinary tract infections, constipation, GI bleeding, cardiovascular disease, stroke and diabetes. In geriatric medicine, the goal is to eliminate or minimize the disease processes that prevent us from living to the natural end of one’s life. Two processes affecting large numbers of geriatric patients are Alzheimer’s disease and rheumatologic problems.

Alzheimer’s disease symptoms were formerly dismissed as consequences of aging but in the 1980s, it was recognized as the most common cause of intellectual deterioration in the elderly and the middle-aged. Its cause is related to the death of nerve cells in the cerebral cortex and generally causes speech disturbances, disorientation and severe short-term memory loss; these lead to progressive loss of mental faculties although the individual remains physically healthy. Two characteristic abnormalities in the cellular structure of the brain tissue include neuritic plaques and neurofibrillary tangles; victims also have a deficiency of the neurotransmitter acetylcholine. Also, Alzheimer’s may be related to a virus, abnormal concentrations of aluminum, a hereditary involvement and/or Down’s syndrome.

Approximately 80% of the population have at least one rheumatologic complaint by their 60’s. These conditions may affect mobility, quality of life and may limit an individual’s ability to live independently. Included in the rheumatologic disease are polymyalgia rheumatica (a syndrome characterized by pain and morning stiffness in the neck, shoulder girdle and pelvic girdle), fibromyalgia (characterized by chronic diffuse muscle pain), giant cell arteritis (temporal arteritis, a vasculitis that involves the aorta and its proximal branches, crystal arthropathies (gout, pseudo-gout, caused by intra-articular deposits of monosodium urate and calcium pyrophosphate in joints) and degenerative joint diseases, including arthritis. Due to the extensive numbers of patients suffering from arthritis, the remainder of this issue will deal specifically with patients suffering from arthritic disease.

**ARTHRITIS**

A 1998 study estimated that 40 million Americans had some form of arthritis; this number is expected to grow to almost 60 million within the next 20 years. Pharmacists are often the first point of contact for patients complaining of painful or stiff joints. They frequently are seeking non-prescription products for self-treatment. What can be recommended for self-treatment and what recommendations can be made to health care practitioners for the patients they treat? First of all, there is currently no cure for arthritis. However, there are products that can be recommended to alleviate many of the painful symptoms associated with the disease. Let’s start by looking at the different types of arthritis.
There are four common types of arthritis as follows: **Osteoarthritis**, also called wear and tear arthritis, primarily occurs as a natural part of the aging process and affects an estimated 20 million Americans. **Rheumatoid arthritis** occurs mostly in women and is a very serious, often crippling, form of the disease, affecting some 2.5 million Americans. **Ankylosing spondylitis** often occurs in young men aged 15 to 40 and can result in a “frozen” spine. Also, a type of arthritis can follow an injury and result in conditions such as tennis elbow and lower back pain.

Osteoarthritis begins when the cartilage covering the ends of bones at the joints becomes rough and patchy. These rough spots progress to the growth of tiny bone spurs initiating a chain reaction of irritation of the muscles, tendons then inflammation followed by pain.

Some forms of arthritis appear to run in families; in fact, genetic markers have been found in the white blood cells of those with rheumatoid arthritis and ankylosing spondylitis. In rheumatoid arthritis, the immune system begins to attack the body itself. This results in tissue inflammation and can be a primary cause of damage, mostly to joints. This inflammation causes heat and swelling and the synovium may be destroyed.

Osteoarthritis is the most common arthropathy in geriatric practice. It is responsible for about 70% of all total knee and 60% of all total hip replacements. These procedures reduce the risk of disability and indirect economic costs to patients and society. As our population continues to age, the costs will escalate since preventive and medical interventions are not yet available. Technically, this generalized osteoarthritis is also defined as a polyarticular illness in a predictable distribution of involvement, including the DIP joints (Heberden’s nodes), PIP joints (Bouchard nodes), the base of the thumb, (first CMC joint), the knees, cervical lumbar spine, and the first MTP joint. It is most common in women, frequently occurring in a pattern of finger and varus medial or patellofemoral knee osteoarthritis. Also, a rapidly destructive arthropathy of the hip is mostly a unilateral arthritis that occurs predominantly in older women. These patients may have osteoarthritis in other joints such as the shoulder or knee that may deteriorate along with a progressive femoral head collapse and resorption of the hip.

Pain associated with arthritis is usually initially use-related. Later, rest or night pain appears in the progression of the disease. Patients also experience stiffness and tenderness.

There is at this time no cure for arthritis but it sometimes just goes into remission. The goals of treatment are to relieve pain and to maintain or improve function. No current interventions are known to actually change the natural history of symptomatic disease. The nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most commonly used to treat the symptoms of arthritis. There is, however, much concern that the use of the NSAIDs is excessive and often leads to side effects, including gastric ulcer and perforation; a means of minimizing these side effects is discussed later. For oral administration, it has been recommended that ibuprofen may be the safest and piroxicam the most hazardous NSAID.

One recent study implicated the NSAIDs in 3% of all hospitalizations among the elderly in England; this was due either to GI toxicity or for heart and renal problems aggravated by the NSAIDs. If oral NSAID therapy is implemented, it should be monitored and periodically reassessed. Also, an alternate route, such as topical NSAID therapy, should be considered. The major risk with NSAIDS has been upper GI toxicity in the elderly, especially gastric ulcer in elderly women resulting in higher rates of bleeding perforation and death from peptic ulcer disease.

Acetaminophen in a dose of 2600 to 4000 mg daily is approximately equivalent to ibuprofen in doses of 1200 to 2400 mg or naprosyn 750 mg per day. The dose of acetaminophen should not exceed 4000 mg daily in otherwise healthy patients; the dose should be halved in patients with mild liver disease and should not be used in patients with advanced liver disease or alcoholism since hepatotoxicity may be potentiated. The COX-2 inhibitors such as Celebrex (celecoxib) and Vioxx (rofecoxib) are also increasingly used and may not have the serious GI side effects associated with the NSAIDs.

Capsaicin cream is often used to treat the symptoms of osteoarthritis in joints; its mechanism of action is thought to be by depletion of substance P (a key molecule in the transmission of pain signals from the body to the spinal cord and eventually the brain) in nerve fibers. It is more effective if continuously used on a daily schedule. Capsaicin is the active enzyme found in hot chili peppers of the genus Capsicum (Oital). Various creams, lotions and gels can be compounded. Generally, immediately after application, capsaicin causes burning; however, some individuals eventually develop a tolerance to this burning irritation. It is used in strengths up to 0.25%.

Methyl salicylate and other topical rubefacients are commonly used by patients purchasing them as nonprescription drugs.

Corticosteroid intra-articular injections are used but often do not provide lasting relief. Dexamethasone sodium phosphate is being increasingly administered using iontophoresis, which is the forced movement of drugs using a small electric current through the skin into the inflamed area using a small iontophoretic device.

Also, gold compounds have been used. In badly damaged joints, surgical replacement with artificial joints is indicated. Researchers are looking for drugs that can stop the inflam-
mation and prevent joint damage; it’s hard to develop a drug to prevent arthritis when the exact cause is not known.

Other treatment modalities include weight loss; an 11.2 pound weight loss over ten years led to a 50% reduction in the risk of developing knee arthritis symptoms. In addition to weight loss, walking, exercise and a proper diet are important. It is also good to explain to the patient the difference between osteoarthritis and the more disabling rheumatoid disease. This will help to relieve their anxiety and improve their outlook on life. Rehabilitation is important to maintain and restore the patient’s ability to function independently.

Rheumatoid arthritis (an autoimmune disease) is quite different from osteoarthritis. The inflammation is first associated with the synovial membrane lining the joint. However, as the disease progresses, the diseased tissue produces collagenase and other enzymes that break down cartilage. In treating rheumatoid arthritis, NSAIDS are often first used but if they do not reduce the pain and swelling after two to four months, disease-modifying antirheumatic drugs are prescribed, including gold salts, hydroxychloroquine, sulfasalazine, methotrexate and etanercept.

**ALTERNATIVE MEDICINES**

Alternative medications commonly used include glucosamine sulfate, chondroitin sulfate, S-adenosylmethionine, fish oil, gamma linolenic acid, green tea and Type II collagen. Some of these natural medications are effective; some more so than others. As is the case with all medications, not all of them work in all patients. Many of the alternative medications are prescribed in various combinations by physicians for compounding by pharmacists. There are numerous dietary recommendations for low fat, vegetarian or near-vegetarian diets.

**COMPOUNDED MEDICATIONS FOR ARTHRITIS**

Many patients and health-care practitioners are unaware of the wide variety of medications that can be compounded for treating arthritis. Many compounded prescriptions are designed to be alternate routes of administration of commonly used drugs. For example, the orally administered NSAIDs can cause gastrointestinal distress which can lead to serious consequences; as an example, NSAID related GI distress causes approximately 20,000 deaths and over 100,000 hospitalizations annually in the United States. Also, it is estimated that 8 to 10% of kidney failures annually in the U.S. are caused by the use of these drugs. However, the NSAIDs can be administered topically and be just as effective while minimizing the potentially disastrous effects associated with oral administration of this class of drugs.

**COMPOUNDED FORMULATIONS FOR ARTHRITIS**

**Solution Examples:**

<table>
<thead>
<tr>
<th>Rx</th>
<th>Indomethacin 4% Topical Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indomethacin</td>
<td>4 g</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>5 mL</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>200 mg</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>100 mg</td>
</tr>
<tr>
<td>Purified water</td>
<td>10 mL</td>
</tr>
<tr>
<td>Alcohol, 95%</td>
<td>qs</td>
</tr>
<tr>
<td>Alcohol</td>
<td>100 mL</td>
</tr>
</tbody>
</table>

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredient.
3. Mix the propylene glycol, sodium lauryl sulfate and purified water together.
4. Disperse the indomethacin in about 80 mL of the alcohol.
5. Add the aqueous phase to the indomethacin dispersion and mix well.
6. Add the hydroxypropyl cellulose and mix well.
7. Add sufficient alcohol to volume and mix well.
8. Package and label.

<table>
<thead>
<tr>
<th>Rx</th>
<th>Dexamethasone Sodium Phosphate 1 mg/mL for Iontophoresis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone sodium phosphate</td>
<td>100 mg</td>
</tr>
<tr>
<td>Sterile water for injection</td>
<td>qs</td>
</tr>
<tr>
<td>Sterile water</td>
<td>100 mL</td>
</tr>
</tbody>
</table>

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh the dexamethasone sodium phosphate.
3. Place in a suitable graduate and add sufficient sterile water for injection to volume.
4. Mix well and pass through a 0.2-micron sterile filter into a sterile container.
5. Package and label.

**Topical Gel (Pluronic-Lecithin Organogel) Examples:**

<table>
<thead>
<tr>
<th>Rx</th>
<th>Capsaicin 0.075%, Ketamine Hydrochloride 2% and Ketoprofen 10% in PLO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsaicin</td>
<td>75 mg</td>
</tr>
<tr>
<td>Ketamine hydrochloride</td>
<td>2 g</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>10 g</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>10 mL</td>
</tr>
<tr>
<td>Lecithin/isopropyl palmitate</td>
<td>22 mL</td>
</tr>
<tr>
<td>Pluronic F-127 30% gel</td>
<td>qs</td>
</tr>
<tr>
<td>Pluronic F-127</td>
<td>100 mL</td>
</tr>
</tbody>
</table>

Note: The lecithin:isopropyl palmitate solution can be prepared by mixing 0.2 g sorbic acid, 50 g of soy lecithin and 50 g of isopropyl palmitate. The Pluronic F-127 solution can be prepared by mixing 0.2 g sorbic acid, 30 g of Pluronic F-127 and sufficient purified water to make 100 mL.

1. Calculate the required quantity of each ingredient for the total quantity to be prepared.
2. Accurately weigh/measure each ingredient.
3. Combine the capsaicin, ketamine hydrochloride and ketoprofen powders.
4. Add sufficient propylene glycol to form a smooth paste.
5. Add the lecithin:isopropyl palmitate solution and mix well.
6. Add sufficient Pluronic F-127 gel to volume and mix well.
7. Package and label.

Note: In this formulation, some active ingredients can easily be omitted and others added as needed.

### Topical Alcoholic Gel Example:

<table>
<thead>
<tr>
<th>Rx</th>
<th>Piroxicam 1% Alcoholic Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Piroxicam</td>
</tr>
<tr>
<td></td>
<td>Hydroxypropyl cellulose</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80</td>
</tr>
<tr>
<td></td>
<td>70% Isopropyl alcohol</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredient.
3. Add the hydroxypropyl cellulose powder to about 91 mL of 70% isopropyl alcohol and mix until a clear gel results.
4. Place the piroxicam powder in a mortar and add the propylene glycol and mix well.
5. Add the polysorbate 80 and mix well.
6. Incorporate the gel vehicle into the piroxicam mixture geometrically and mix until uniform.
7. Add sufficient 70% isopropyl alcohol to volume and mix well.
8. Package and label.

### Topical Cream Example:

<table>
<thead>
<tr>
<th>Rx</th>
<th>Capsaicin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capsaicin</td>
</tr>
<tr>
<td></td>
<td>Methyl salicylate</td>
</tr>
<tr>
<td></td>
<td>Menthol</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80</td>
</tr>
<tr>
<td></td>
<td>Dermabase™ qs</td>
</tr>
</tbody>
</table>

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredient.
3. Dissolve the menthol in the methyl salicylate.
4. Mix the capsaicin with the polysorbate 80.
5. Mix the two liquids from steps 3 and 4 together.
6. Slowly incorporate the resulting mixture into the Dermabase.
7. Package and label.

### Topical Ointment Example:

<table>
<thead>
<tr>
<th>Rx</th>
<th>Capsicum 5% Ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capsicum</td>
</tr>
<tr>
<td></td>
<td>Aquabase™</td>
</tr>
</tbody>
</table>

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh each ingredient.
3. Make a paste by incorporating a small quantity of the Aquabase into the capsicum.
4. Slowly incorporate the remaining Aquabase into the paste geometrically.
5. Mix until uniform.
6. Package and label.

### Medication Stick Example:

<table>
<thead>
<tr>
<th>Rx</th>
<th>Analgesic Medication Stick</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Methyl salicylate</td>
</tr>
<tr>
<td></td>
<td>Menthol</td>
</tr>
<tr>
<td></td>
<td>Sodium stearate</td>
</tr>
<tr>
<td></td>
<td>Purified water</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
</tbody>
</table>

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh/measure each ingredient.
3. Mix the sodium stearate, purified water and propylene glycol and melt.
4. Mix thoroughly, remove from heat and allow to cool for a few minutes.
5. Dissolve the menthol in the methyl salicylate and add to the melted base and thoroughly mix.
6. Allow to cool further until it just begins to thicken.
7. Pour into medication stick containers and allow to harden.
8. Label.

### REFERENCES

### SUGGESTED READING
Table 1: Drugs Commonly Used in Treating Gastrointestinal Disorders

<table>
<thead>
<tr>
<th>Condition</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>Methocel, mineral oil</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Loperamide, diphenoxylate</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>Ranitidine, omeprazole</td>
</tr>
<tr>
<td>Dysphoria</td>
<td>Loperamide, diphenoxylate</td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>Loperamide, diphenoxylate</td>
</tr>
<tr>
<td>Hemorrhoids</td>
<td>Vancomycin, metronidazole</td>
</tr>
<tr>
<td>Heartburn</td>
<td>Ranitidine, omeprazole</td>
</tr>
<tr>
<td>Indigestion</td>
<td>Docusate, bisacodyl</td>
</tr>
<tr>
<td>Irritable bowel syndrome</td>
<td>Metamucil, Senokot</td>
</tr>
<tr>
<td>Ulcers</td>
<td>H2 blockers, PPIs</td>
</tr>
</tbody>
</table>


3. The function of the large intestine is to:

   a. Absorb water
   b. Absorb nutrients
   c. Produce enzymes
   d. Absorb gas
   e. Produce hormones

4. The major functions of the stomach are:

   a. Storage
   b. Digestion
   c. Production of enzymes
   d. Absorption of nutrients
   e. All of the above

5. Which of the following enzymes aids in the breakdown of starch?

   a. Amylase
   b. Trypsin
   c. Lipase
   d. Pancreatin
   e. All of the above

6. The normal pH of the stomach is typically:

   a. 1-2
   b. 3-4
   c. 5-6
   d. 7-8
   e. 9-10

7. The normal temperature of the stomach is typically:

   a. 37°C
   b. 38°C
   c. 39°C
   d. 40°C
   e. 41°C

8. The normal volume of the stomach is typically:

   a. 500 mL
   b. 1000 mL
   c. 1500 mL
   d. 2000 mL
   e. 2500 mL

9. The feeling of nausea can arise from which of the following area(s) of the body?

   a. GI tract
   b. Liver
   c. Kidney
   d. Pancreas
   e. All the above

10. Treatment of constipation may involve:

    a. Increase fiber intake
    b. Use of stool softeners
    c. Use of laxatives
    d. Use of enemas
    e. All of the above

11. Common causes of constipation include:

    a. inadequate dietary fiber
    b. inadequate fluid intake
    c. medications that affect bowel motility
    d. all of the above
    e. none of the above

12. The quality of the information presented in this article was:

    a. Excellent
    b. Fair
    c. Good
    d. Poor
    e. Very Poor

13. The feeling of heartburn is:

    a. Chest pain
    b. Acid reflux
    c. Esophageal spasm
    d. Gastric distension
    e. All of the above

14. The role of the stomach is to:

    a. Digest food
    b. Absorb nutrients
    c. Produce enzymes
    d. Produce acid
    e. All of the above

15. The mechanism of action of acid suppression drugs is:

    a. Reduce acid production
    b. Block H+ secretion
    c. Neutralize stomach contents
    d. All of the above
    e. None of the above

Introduction: There are many disorders involving the gastrointestinal (GI) tract, including a variety of conditions such as constipation, diarrhea, dyspepsia, heartburn, gas, nausea and vomiting. Disorders of the GI tract involve the alimentary canal and its accessory organs. The alimentary canal begins at the mouth and extends to the anus, and includes the pharynx, esophagus, stomach, small and large intestines, and rectum. This lesson is no longer valid for CE credit after 02/28/08.

Anatomy and Physiology: The GI system consists of the alimentary canal and the accessory organs. The alimentary canal begins at the mouth and includes the pharynx, esophagus, stomach, small intestine, and large intestine. The accessory organs include the liver, pancreas, gallbladder, and spleen. Disorders of the GI tract may affect any part of the alimentary canal, including the mouth, pharynx, esophagus, stomach, small intestine, large intestine, and rectum. Disorders of the accessory organs may affect the liver, pancreas, and gallbladder.

GOALS AND OBJECTIVES

Goal: To provide pharmacists with background, treatment and compounding options for gastrointestinal disorders.

Objectives:

1. Discuss the basic anatomy and physiology of the gastrointestinal tract.
2. List at least five general gastrointestinal tract disorders.
3. Describe general methods of treating gastrointestinal disorders.
4. Discuss active ingredients as well as several compounded formulas used in treating common gastrointestinal disorders.

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Current & Practical Compounding

COMPOUNDING FOR GASTROINTESTINAL DISORDERS

Gastrointestinal tract disorders are very common. They can be caused by a variety of factors, including diet, medications, underlying medical conditions, and infections. The symptoms of gastrointestinal disorders can range from mild to severe and may include constipation, diarrhea, dyspepsia, heartburn, gas, nausea, and vomiting. This lesson is no longer valid for CE credit after 02/28/08.

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Infection, pancreatic disease, biliary and sickness that may or may not include vomiting. Vomiting sometimes the production of gas, especially hydrogen, carbon dioxide and from either swallowed air or bacterial fermentation of undigested car-

Stomach, the lower esophageal sphincter is relaxed. Belching is normal or eructation, can be either involuntary or voluntary and involves theintestinal gas
digestion of food. Foods may produce gas by fermentation of carbohydrates and are released from the anus; the rate and volume is highly variable. Flatus results

It has been defined as pain or Dyspepsia occurs in about one-fourth of the adult population and most commonly caused by infectious agents, bacterial toxins or drugs. Acute onset vomiting may be caused by peri-

FORMULATIONS FOR TREATING GASTROINTESTINAL DISORDERS

It is valid scientific information to support the stability of the product. The following beyond-use recommendations can be exceeded if there is

Gastrointestinal Disoders

For all other products, the beyond-use recommendation is the intend-

Sterility and Beyond-use dates for water-containing formulations are no later than

QUALITY CONTROL

For dyspepsia and heartburn generally include oral solids and liq-

STEADIBILITY AND BEYOND-USE DATES FOR GASTROINTESTINAL DISORDERS

The following beyond-use recommendations can be recorded if there is complete information to report. If there are no stability data on file or after

Dyspepsia occurs in about one-fourth of the adult population and most commonly caused by infectious agents, bacterial toxins or drugs. Acute onset vomiting may be caused by peri-

FORMULATIONS FOR TREATING CONSTIPATION

Most cases of acute vomiting are mild, self-limited and really require

The intestinal tract, whereas in the stomach, the lower esophageal sphincter is relaxed. Belching is normal or eructation, can be either involuntary or voluntary and involves the

Infection, pancreatic disease, biliary and sickness that may or may not include vomiting. Vomiting sometimes the production of gas, especially hydrogen, carbon dioxide and from either swallowed air or bacterial fermentation of undigested car-

Dyspepsia and heartburn can generally be treated by a reduction in

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Quality

For dyspepsia and heartburn generally include oral solids and liq-

Gastroenteritis or acute duodenal ulcer (the population health impacts are estimated at a per person level of $10,000) is a disease that is defined as present in 1%

Gastrointestinal Disoders

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Quality

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H. pylori and movements). The medullary vomiting center that causes vomiting can result in more flatus, including those containing fructose, lactose, and does not usually indicate a GI dysfunction. Flatus is escape of gases from either swallowed air or bacterial fermentation of undigested carbohydrates. Gas in the stomach can escape from the GI tract either as belching or flatus. Belching, although infrequent, is a natural and common response to air swallowing. Flatus is a more frequent and common occurrence.

**Gas can escape from the GI tract either as belching or flatus.** Belching, although infrequent, is a natural and common response to air swallowing. Flatus is a more frequent and common occurrence.

**Intestinal Gas**

Gas can escape from the GI tract either as belching or flatus. Belching, although infrequent, is a natural and common response to air swallowing. Flatus is a more frequent and common occurrence.

**Diarrhea**

Diarrhea is a frequent bowel movement, but it may result in more flatus, including those containing fructose, lactose, and does not usually indicate a GI dysfunction. Flatus is escape of gases from either swallowed air or bacterial fermentation of undigested carbohydrates. Gas in the stomach can escape from the GI tract either as belching or flatus. Belching, although infrequent, is a natural and common response to air swallowing. Flatus is a more frequent and common occurrence.

Diarrhea may also be caused by GI tract dysfunction (peptic ulcer disease), dysmotility, psychogenic or CNS system disorders. Vomiting immediately after meals may be a result of bulimia or pregnancy, gastric outlet obstruction, gastroparesis, intestinal pseudo-obstruction, inflammatory bowel disease, the use of certain medications or drugs, radiation therapy, acidosis, and acute pancreatitis. 

**Quality Control**

The compounding pharmacist should follow standard quality control procedures. These include checking the volume/weight, pH, viscosity, sterility and appearance of all compounded preparations. If necessary, the pharmacist should adjust the pH or appearance and add or subtract one of the compounded preparations.

**STABILITY AND BEYOND-USE DATES FOR GASTROINTESTINAL DISORDERS**

The following beyond-use recommendations can be recorded either in a separate log book or on the stability label or in the compounding pharmacist’s log:

- **Nausea and Vomiting**
  - One strength of metoclopramide (Beano) that will reduce gas caused by foods containing raffinose (garlic, onion, eggplant, mushrooms and certain herbs and spices). Parsnips, onions, beer and coffee. Foul odor flatus may be caused by bacteria in the colon that ferment indigestible matter from the bowel. Acute onset diarrhea lasting less than 3 weeks is managed with oral rehydration therapy. Antidiarrheal agents include kaopectate (Kaopectate) and anti-emetics such as promethazine and diphenoxylate. Polyethylene glycol 6000 (M equivalent to 10 mg/kg body weight). Add sufficient partial volume to volume mix and mix well. Package and label.

- **Acute Onset Diarrhea**
  - Add all of the ingredients to a Pyrex bottle and add sufficient water to volume mix and mix well. Package and label.

**TREATMENT OF GASTROINTESTINAL DISORDERS**

**Dyspepsia and Heartburn**

Heartburn may also be caused by GI tract dysfunction (peptic ulcer disease). It is often caused by acid reflux, achalasia, pyloric stenosis, gastroparesis, and esophageal motility disorders. 

**Dyspepsia**

Dyspepsia is a vague and very disagreeable sensation of queasiness or nausea and does not usually indicate a GI dysfunction. Flatus is escape of gases from either swallowed air or bacterial fermentation of undigested carbohydrates. Gas in the stomach can escape from the GI tract either as belching or flatus. Belching, although infrequent, is a natural and common response to air swallowing. Flatus is a more frequent and common occurrence.

**Anticholinergic**

Anticholinergic medications such as scopolamine (transdermal), hyoscine (transdermal), benzatropine, and diphenoxylate are used to treat nausea and vomiting. These medications work by delaying gastric emptying and slowing intestinal transit. Anticholinergic medications may cause dry mouth, constipation, blurred vision and difficulty urinating.

**Antiemetic**

Antiemetic medications such as promethazine, dimenhydrinate and loperamide hydrochloride are used to treat nausea and vomiting. These medications work by slowing gastric emptying and delaying intestinal transit. Antiemetic medications may cause dry mouth, constipation, blurred vision and difficulty urinating.

**Antidiarrheal**

Antidiarrheal medications such as loperamide hydrochloride, bismuth subsalicylate and diphenoxylate with atropine are used to treat acute diarrhea lasting less than 3 weeks. Antidiarrheal medications may cause dry mouth, constipation, blurred vision and difficulty urinating.

**Antibiotic**

Antibiotic medications such as amoxicillin, metronidazole and clindamycin are used to treat diarrhea caused by infections with Clostridium difficile. Antibiotic medications may cause diarrhea, abdominal pain, headache, dizziness, rash, and rash with bleeding.

**Formulations for Treating Nausea and Vomiting**

**Anticholinergic**

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**Anticholinergic**

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**Antiemetic**

Antiemetic medications such as promethazine, dimenhydrinate and loperamide hydrochloride are used to treat nausea and vomiting. These medications work by slowing gastric emptying and delaying intestinal transit. Antiemetic medications may cause dry mouth, constipation, blurred vision and difficulty urinating.

**Antidiarrheal**

Antidiarrheal medications such as loperamide hydrochloride, bismuth subsalicylate and diphenoxylate with atropine are used to treat acute diarrhea lasting less than 3 weeks. Antidiarrheal medications may cause dry mouth, constipation, blurred vision and difficulty urinating.
Nausea and Vomiting

Nausea is a vague and very disagreeable sensation of queasiness or distress, accompanied by feelings of gastric distention or by the urge to vomit. It can be caused by a variety of factors, including:

- Excessive intake of food or drink
- Digestive disorders such as peptic ulcer disease or irritable bowel syndrome
- Drugs or medications
- Alcohol or other substances
- Emotional stress or anxiety
- Prolonged fasting or starvation
- Certain foods or ingredients

Treatment of Nausea and Vomiting

Acute nausea and vomiting can usually be managed by:

- Resting and avoiding any further intake of food or drink
- Drinking small amounts of clear liquids (water, broth, or ginger ale)
- Avoiding strong-smelling foods and odors
- Practicing relaxation techniques
- Using over-the-counter antinausea medications

Medical treatment may be necessary in cases of severe or prolonged nausea and vomiting, especially when accompanied by signs of dehydration, electrolyte imbalances, or other complications.

Intestinal Gas

Intestinal gas is the result of swallowed air, fermentation of food by gut bacteria, and the absorption of gases from the environment. It is a natural and necessary part of digestion. However, excessive gas can cause discomfort and may lead to symptoms such as bloating, pain, and flatulence.

Factors that can contribute to excessive intestinal gas include:

- Eating too quickly or while chewing
- Eating foods that are difficult to digest
- Drinking carbonated beverages
- Smoking
- Emotional stress

Management of Intestinal Gas

To manage symptoms of excess gas, consider:

- Practicing good oral hygiene
- Chewing food slowly and thoroughly
- Limiting the intake of gas-producing foods
- Avoiding carbonated drinks
- Reducing stress and practicing relaxation techniques

Naloxone and Nalbuphine

Naloxone and nalbuphine are opioid receptor antagonists that can be used to treat opioid overdose, respiratory depression, and other opioid-related conditions. They work by blocking the effects of opioids at the opioid receptor sites in the brain and spinal cord, which can reverse the symptoms of overdose.

Dosage Forms for Naloxone and Nalbuphine

Naloxone and nalbuphine are available in various forms, including:

- Oral solutions
- Intravenous solutions
- Nasal sprays
- Intra-muscular injections

For more detailed information on dosage forms and administration, please refer to the respective product monographs or consult with a medical professional.

FORMULATIONS FOR TREATING NAL DISORDERS

FORMULATIONS FOR TREATING NAL DISORDERS

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Active Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone Hydrochloride 0.4 mg/mL Nasal Solution</td>
<td>Naloxone hydrochloride 0.4 mg/mL</td>
</tr>
<tr>
<td>Naloxone Hydrochloride 0.8 mg/mL Nasal Solution</td>
<td>Naloxone hydrochloride 0.8 mg/mL</td>
</tr>
</tbody>
</table>

Additional formulations may be available and can be found in the respective product monographs. Always consult with a medical professional for the appropriate dosage and administration route.

Fluticasone Propionate

Fluticasone propionate is a corticosteroid used to treat various conditions, including asthma, chronic obstructive pulmonary disease (COPD), and allergic rhinitis. It works by suppressing the immune response and reducing inflammation in the airways and nasal passages.

Dosage Forms for Fluticasone Propionate

Fluticasone propionate is available in several forms, including:

- Oral solutions
- Inhalers
- Nasal sprays

For more detailed information on dosage forms and administration, please refer to the respective product monographs or consult with a medical professional.

FORMULATIONS FOR TREATING ASTHMA

FORMULATIONS FOR TREATING ASTHMA

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Active Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluticasone Propionate 25 mcg/actuation Inhaler</td>
<td>Fluticasone propionate 25 mcg/actuation</td>
</tr>
</tbody>
</table>

Additional formulations may be available and can be found in the respective product monographs. Always consult with a medical professional for the appropriate dosage and administration route.

Conclusion

Managing nausea, vomiting, and intestinal gas can be challenging, but with the right approach and treatment, these conditions can be effectively managed. Whether through lifestyle changes, dietary adjustments, or medication, there are options available to help alleviate symptoms and improve overall well-being.
**Rx Scopolamine 0.25 mg/0.1 mL in Pluronic Lecithin Organogel**

1. Mix the promethazine hydrochloride with the propylene glycol to a smooth paste. Add the lecithin:isopropyl palmitate solution and mix well. Incorporate the mixing method. Package and label.

2. Mix the Pluronic F127 gel with the Pluronic Lecithin Organogel and mix well. Add sufficient about 50 mL of the Pluronic F127 gel and mix well. Incorporate the mixing method. Package and label.

3. Place the medication stick molds/containers into medication stick molds/containers. Package and label.

---

**Table 1: Drugs Commonly Used in Treating Gastrointestinal Disorders**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Active Ingredient(s)</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scopolamine Hydrobromide</td>
<td>(200 mcg/100 mg)</td>
<td>Medication Stick</td>
</tr>
<tr>
<td>Metoclopramide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dicyclomine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyoscine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dextromethorphan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OxyContin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Secundum Artem**

**Current & Practical Compounding Information for the Pharmacist**

**Volume 13 Number 2**

**COMPOUNDING FOR GASTROINTESTINAL DISORDERS**

**Goal:** To provide pharmacists with background, treatment and compounding options for gastrointestinal disorders.

**Objectives:** After reading and studying the article, the reader will be able to:
1. Discuss the basic anatomy and physiology of the gastrointestinal tract.
2. List at least five general gastrointestinal tract disorders.
3. Describe general methods of treating gastrointestinal disorders.
4. Discuss active ingredients as well as several compounded formulae used in treating common gastrointestinal disorders.

**Introduction:**

There are many disorders involving the gastrointestinal (GI) tract, varying in terms of both severity and the type of treatment. Some of the GI tract disorders can be alleviated through several means, whereas others require more intensive medical intervention. The GI tract has a tremendous influence on all other parts of the body, and its medical condition can affect overall health and well-being. The GI tract is responsible for the digestion and absorption of nutrients, the removal of waste products, and the elimination of excess water and electrolytes. The GI tract also plays a crucial role in the immune system, as it is responsible for the production of white blood cells that fight infection.

**Common Gastrointestinal Disorders**

The most common gastrointestinal disorders include:

- **Constipation:** Ineffective peristaltic activity, decreased water and electrolyte absorption, and inadequate fiber or fluid intake, poor bowel habits, systemic disease, medications, and altered diet.
- **Diarrhea:** Increased peristaltic activity, increased water and electrolyte absorption, and increased bowel movements.
- **Dyspepsia:** Poor digestion and absorption, prolonged gastric emptying, and increased abdominal gas.
- **Heartburn:** Increased gastric acid production, increased esophageal sphincter hypotonia, and increased food and fluid intake.
- **Indigestion:** Poor digestion and absorption, prolonged gastric emptying, and increased abdominal gas.
- **Nausea:** Increased gastric acid production, increased esophageal sphincter hypotonia, and increased food and fluid intake.
- **Vomiting:** Increased gastric acid production, increased esophageal sphincter hypotonia, and increased food and fluid intake.

The GI tract is a complex, highly specialized system responsible for the absorption of nutrients, the elimination of waste products, and the regulation of electrolyte balance. Disorders of the GI tract can affect various aspects of the system, including the absorption of nutrients, the excretion of waste products, and the regulation of electrolyte balance. The GI tract is also involved in the regulation of the body's pH balance, as it is responsible for the production of stomach acid, which is necessary for the proper digestion of food. The GI tract is also involved in the regulation of the body's immune system, as it is responsible for the production of white blood cells that fight infection.

**Conclusion:**

The GI tract is a complex, highly specialized system responsible for the absorption of nutrients, the elimination of waste products, and the regulation of electrolyte balance. Disorders of the GI tract can affect various aspects of the system, including the absorption of nutrients, the excretion of waste products, and the regulation of electrolyte balance. The GI tract is also involved in the regulation of the body's pH balance, as it is responsible for the production of stomach acid, which is necessary for the proper digestion of food. The GI tract is also involved in the regulation of the body's immune system, as it is responsible for the production of white blood cells that fight infection.

---

**SEND THIS COMPLETED FORM IN FOR CE CREDIT TODAY!**

**Please circle the most appropriate answer for each of the following questions.**

1. The gastrointestinal system consists of the:
   - a. mouth
   - b. mouth, stomach, large intestine
   - c. mouth, stomach, small intestine
   - d. all above
   - e. none of the above

2. The purpose of the gastrointestinal system is to:
   - a. digest food and break down into simple nutrients
   - b. absorb water, secrete mucus, eliminate digestive wastes
   - c. absorb water, secrete mucus, eliminate digestive wastes, provide immunity, transport foodstuff throughout the body
   - d. all above
   - e. none of the above

3. The ability to absorb nutrients from the food the body is:
   - a. I only
   - b. III only
   - c. I and II only
   - d. II and III only
   - e. I, II and III

4. If one has ______ bowel movements _____, he/she may be experiencing:
   - a. constipation
   - b. diarrhea
   - c. normal bowel movements
   - d. III only
   - e. none of the above

5. Approximately how many liters of fluid enter the digestive tract daily?
   - a. 1
   - b. 5
   - c. 10
   - d. 15
   - e. none of the above

6. Components of intestinal gas may include:
   - a. swallowed air
   - b. methane
   - c. 6
   - d. II and III only
   - e. I, II and III

7. The feeling of nausea can arise from which of the following area(s) of the body?
   - a. GI tract
   - b. vestibular system
   - c. I and II only
   - d. II and III only
   - e. I, II and III

---

**References:**

- 3. Dr. Allen is not affiliated with Paddock Laboratories Inc.
The gastrointestinal system consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract serves two major functions: (1) to digest food and absorb nutrients from digested foods and (2) to eliminate or excrete waste products through excretion stool. Causative factors for constipation include inadequate dietary fiber and fluid intake, lack of physical activity, medications, and certain medical or surgical conditions. Constipation has been defined as having two or fewer bowel movements a week or when there is excessive difficulty and straining during defecation. There are a few subtypes of constipation, including slow transit constipation, pseudo-obstruction, and rectoceles. The symptoms of constipation may be recognized during their occurrence, i.e., nausea, vomiting, diarrhea, heartburn and dyspepsia. There are many treatment options available including those that can be compounded for specific patients. Some effective options have been discontinued over time but others can be traded available through compounding.

**ANATOMY AND PHYSIOLOGY**

The GI system consists of the alimentary canal and the accessory organs. For an entire week, the GI tract absorbs the nutrients from digested foods and processes the wastes that cannot be absorbed within the body. The digestive system is an important organ system responsible for breaking down ingested food and secreting digestive enzymes to the contents of the gastrointestinal tract. The GI tract manifests itself in various ways with different symptoms. In general, they tend to modify our behavior and lifestyle and produce changes in the symptoms, however, bowel movements range from three to twelve per week. What is the frequency of "normal" bowel movements? If one listens to our ancestors and our forefathers, it is expected that their diet was composed of food that was provided by the land, hence they had their food from the diet that they consumed during their journey to the land. Nowadays, the bread and the fruit from the diet that they consumed during their journey to the land is highly processed, and we have been consuming a variety of foods that are not natural. These foods include bread, pasta, rice, and many other processed foods. These foods contain a lot of sugar and fat, which can cause constipation. The GI system consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI system consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI system consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI system consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.).

**COMMON GASTROINTESTINAL DISORDERS**

- **Constipation**
- **Diarrhea**
- **Nausea and Vomiting**
- **Intestinal Gas**

**GASTROINTESTINAL DISORDERS**

**INTRODUCTION**

There are many disorders involving the gastrointestinal (GI) tract, a long and very complex organ system. One can find that the GI tract involves the liver, gall bladder, pancreas, etc. Some effective options have been discontinued over time but others can be traded available through compounding.

**GOALS AND OBJECTIVES**

- Discuss the basic anatomy and physiology of the gastrointestinal tract.
- Discuss general methods of treating gastrointestinal disorders.
- Discuss active ingredients as well as several compounded formulations used in treating common gastrointestinal disorders.

**REFERENCES**


**EXPERIMENTAL METHODS**

The first step is to prepare the Pluronic F127 gel and mix well. Allow to cool until it starts to thicken then pour the Pluronic into the shearing action mixing method. Package and label.

**COMPOUNDING FOR GASTROINTESTINAL DISORDERS**

**APPLICATIONS**

- Constipation
- Diarrhea
- Nausea and Vomiting
- Intestinal Gas

**CONCLUSION**

The gastrointestinal tract is an important organ system responsible for breaking down ingested food and secreting digestive enzymes to the contents of the gastrointestinal tract. The GI tract manifests itself in various ways with different symptoms. In general, they tend to modify our behavior and lifestyle and produce changes in the symptoms during their occurrence, i.e., nausea, vomiting, diarrhea, heartburn and dyspepsia. There are many treatment options available including those that can be compounded for specific patients. Some effective options have been discontinued over time but others can be traded available through compounding.

**ANATOMY AND PHYSIOLOGY**

The GI system consists of the alimentary canal and the accessory organs. The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.). The GI tract consists of the alimentary canal and the accessory organs (liver, gall bladder, pancreas, etc.).

**COMMON GASTROINTESTINAL DISORDERS**

- **Constipation**
- **Diarrhea**
- **Nausea and Vomiting**
- **Intestinal Gas**
INTRODUCTION
Did you know that in the United States;\(^1\)

1. Diabetes is one of the most costly health problems. The total costs, including health care and direct diabetes treatment costs as well as lost productivity, in 1997, ran 98 billion dollars. This includes 44 billion dollars in direct medical and treatment costs and 54 billion dollars in indirect costs attributed to disability and mortality. About 8.2\% of all men and about 8.1\% of all women in the U.S. have diabetes (undiagnosed in about 1/3 in both sexes).

2. There are 15.7 million diabetics in the U.S. (about 5.9\% of the total population), including 10.3 million diagnosed diabetics and 5.4 million undiagnosed diabetics.

3. Daily, about 2,200 people are diagnosed with diabetes.

4. Diabetes is the 7th leading cause of death.

5. Diabetes is the leading cause of new cases of blindness in adults age 20-74, with 12,000 to 24,000 diabetics annually losing their sight because of diabetes.

6. Ten to 21\% of diabetics develop kidney disease; diabetes is the leading cause of end-stage renal disease, responsible for about 40\% of all new cases.

7. More than 56,000 amputations occur annually because of diabetes.

8. There are more than 77,000 diabetic deaths due to heart disease annually as a result of diabetes.

9. Diabetic nerve damage, which can lead to lower limb amputations occurs, in about 60-70\% of diabetics. About 56,200 diabetics lose a foot or leg to diabetes annually.

10. Impotence affects about 13\% of male Type I diabetics and 8\% of male Type 2 diabetics. Over the age of 50, impotence rates as high as 50-60\% have been reported.

11. About 10.8\% of all African Americans have diabetes (undiagnosed in about 1/3 of them).

12. About 10.6\% of all Mexican Americans have diabetes.

13. About 12.2\% of Native Americans over 19 years of age have Type 2 diabetes.

14. About half of all diabetes cases occur in seniors 55 years and older.

DEFINITIONS
Diabetes is defined as a chronic syndrome characterized by abnormally high blood glucose levels and by defects in insulin production or utilization.\(^2\) As can be seen from that definition, diabetes is not described as a single disease but as a “syndrome”, composed of several specific diseases that are all characterized by hyperglycemia and a tendency to develop macro- and microvascular disease and neuropathy.

Under ordinary conditions, the cooperation and synergy of glucagon, somatostatin, growth hormone, cortisol, epinephrine and other hormones and endogenous insulin serve to maintain blood glucose levels between 50 and 150 mg/mL (mg\%).\(^2\) In the pancreas, the beta cells produce insulin and the alpha cells produce glucagon, the major hormones in control of glucose metabolism. When plasma glucose levels rise, as
after a meal, the pancreatic beta cells release insulin and the liver clears the hormone from the system. The insulin stimulates glucose storage in muscle and liver cells as glycogen, increases synthesis of fatty acids and triglycerides, decreases hepatic glucose output, stimulates lipolysis and production of ketone bodies and enhances incorporation of amino acids into proteins. Opposite to this, glucagon is released from the pancreatic alpha cells as a result of low blood glucose or high amino acid levels. This causes the breakdown of glycogen into glucose in the liver and a resultant rise in the blood glucose level.2

When all the systems are properly functioning, homeostasis and good health results. However, when the systems malfunction, diabetes can result. Some factors that are associated with the onset of diabetes include heredity, obesity, age, stress, hormonal imbalance, vasculitis of pancreatic blood supply vessels and viruses affecting the autoimmune responses of the body.3

TYPES OF DIABETES

There are four types of diabetes. "Type I" (5-10% of diabetic patients) generally occurs during childhood or adolescence with an abrupt onset. Its primary cause is a pancreatic beta-cell deficiency resulting in impaired or absent insulin secretion. It is an auto-immune disorder and presenting symptoms include weight loss, tiredness, polydipsia, polyphagia, polyuria and possibly visual difficulties. Insulin is required in these patients. In addition, treatment includes a healthy diet (low in fat, moderate amounts of protein, high in complex carbohydrates) and exercise. A type I diabetic requires exogenous insulin to survive and maintain a healthy lifestyle; hence the name Insulin Dependent Diabetes Mellitus (IDDM).

"Type II" (85-90% of diabetic patients) generally occurs after about 35 years of age with a gradual onset. It commonly occurs in families with a history of diabetes. Its primary cause, a metabolic disorder, is either the insulin receptors become unresponsive to the action of insulin or there may be an insulin deficiency. Type II diabetes is nearly epidemic, probably due to an increased number of living older Americans and a greater prevalence of obesity and sedentary lifestyles. Type II diabetes is more common among African Americans, Latin Americans and Native Americans. In the Type II diabetic, the pancreas is usually producing insulin, but the body cannot utilize it properly, resulting in hyperinsulinemia and hyperglycemia. Interestingly enough, Type II diabetics may be symptom-free, at least in the initial stage of the disease. Insulin may be necessary in up to 20-30% of patients; others may be controlled by diet/exercise or by oral hypoglycemic agents. It has also been called Non-Insulin Dependent Diabetes Mellitus (NIDDM).

"Gestational onset diabetes" may occur in about 2-5% of pregnancies but is generally temporary, disappearing after delivery. It becomes evident after about 24 to 28 weeks of pregnancy. Of concern is that about 40% of these patients may progress to Type 2 diabetes.

"Other" (1-2% of diabetic patients) diabetics may result from a number of causes, including malnutrition, surgery, drugs, infections and other illnesses.

TREATMENT

Treatment of diabetes includes both pharmacologic and nonpharmacologic measures. Pharmacologic measures involve insulin and the oral hypoglycemic agents. Today's insulin is available in a form identical to human insulin and is available in immediate acting and long acting forms. Mixtures can be prepared to tailor the insulin to the patient's needs. Pharmacologic measures also include the oral hypoglycemic agents, the sulfonylureas, biguanide, alpha glucosidase inhibitors, thiazolidinediones and meglitinide.

The sulfonylureas, glipizide (Glucotrol SL), tolbutamide (Orinase), tolazamide (Tolinase), glyburide (Diabeta) and glimepiride (Amaryl) act by stimulating the release of insulin from the pancreatic beta cells.

The biguanide, metformin (Glucophage) acts by decreasing liver glucose output and inducing a minor decrease in insulin resistance.

The alpha glucosidase inhibitors acarbose (Precose) and miglitol (Glyset) act by slowing the absorption of carbohydrates form the gastrointestinal tract.

The thiazolidinediones, or glitazones, pioglitazone-(Actos), and rosiglitazone (Avandia) act by decreasing insulin resistance and increasing insulin sensitivity.

Meglitinide, repaglinide (Prandin) acts by increasing insulin release from the pancreas.

Nonpharmacologic therapy has been divided into 5 categories: education, exercise, diet, blood glucose self-monitoring and others. Others include annual visits to an ophthalmologist and podiatrist, abstaining from smoking, monitoring blood pressure and blood lipids, patient assessment annually for the development of chronic diabetes complications and proper examination and care of the feet.3

Educational programs should include topics such as diet, exercise, self-monitoring of blood glucose, drug therapy, psychosocial issues, sick day activities, symptoms, hypoglycemia treatment and other patient-specific information.

Exercise is very important as it can aid in reducing blood glucose and improve circulation, generally resulting in a greater sense of well-being. Exercise activities at least three times weekly of the aerobic type are recommended. Exercise will also aid in achieving and maintaining normal body weight. The onset of Type 2 diabetes may be prevented or delayed by reducing lifestyle risk factors through weight loss and increased physical activity.

Diet therapy should include discussions of daily caloric intake, reduction of dietary fat (especially animal fats), increasing dietary fiber, moderating sodium and alcohol consumption as well as the daily intake of a vitamin/mineral/trace element supplement.

Self-monitoring of blood glucose is recommended by the American Diabetic Association. Consequently, patients need to be educated on drawing blood and how to correctly use, calibrate, clean and store their blood glucose meters.

COMPLICATIONS

Diabetes can result in three general types of problems: ketoacidosis, hypoglycemia and other complications. Pharmacists have been focusing on the prevention and treatment of ketoacidosis and hypoglycemia for years; today, there is increased emphasis on the prevention and treatment of complications from the disease. Complications in common with both Type 1 and Type 2 diabetics include retinopathy, neuropathy, renal failure and lower extremity disease.
Diabetic complications have been described as microvascular (involving retinopathy and nephropathy), macrovascular (including atherosclerosis and arteriosclerosis) and neuropathic. Neuropathic is further categorized as peripheral and autonomic. Peripheral neuropathy involves loss of function of nerves in the hands, feet and other peripheral tissues. Autonomic neuropathy involves loss of function of the nerves of the autonomic nervous system that can result in gastroparesis, constipation and other gastrointestinal and cardiovascular symptoms.

These complications provide the compounding pharmacist with numerous opportunities for compounding individualized medications, as detailed in the formulas presented later. According to Paul Lofholm, Pharm.D., the three primary types of formulations being compounded include insulin mixtures, sugar-free preparations and foot-care preparations.

**PHARMACISTS WORKING WITH PATIENTS**

Services that pharmacists can provide to diabetic patients include:

1. Educating them about diabetes, its causes, symptoms, prevention and treatment.
2. Diabetic ketoacidosis; its causes, symptoms, prevention and treatment.
5. Proper care of the feet.
6. Proper care of the eyes.
7. Proper care of the skin.
8. Use of blood glucose monitoring devices, their operation, care and cleaning.
9. Use of diabetic supplies, including lancets, alcohol swabs, syringes and insulin.
10. Use of glucose gels, glucose tablets and glucagon.
11. How to care for, mix and inject insulin.
12. Pre-filling insulin syringes; storage, handling and use.

Primary outcomes for which pharmacists can be actively involved in treating diabetes include preventing or relieving symptoms of diabetes, especially the complications. Self-care is vital to the proper treatment of diabetes. This can be enhanced and encouraged by pharmacists through educational programs and regular monitoring of the patients’ medication needs and compliance.

**TIGHT CONTROL**

"Tight Control" is a program of intensive monitoring and maintenance of blood-glucose levels within narrow limits utilizing diet, oral medication or insulin. A special study, known as the Diabetes Control and Complications Trial (DCCT) showed that patients achieving tight control experienced a 50% reduction in the incidence of debilitating diabetes complications such as retinopathy, nephropathy and neuropathy. These study results were confirmed 5 years later in the United Kingdom Prospective Diabetes Study.

The results of the studies have demonstrated that metabolic control is crucial and this should impact the diabetes health-care system to intensify treatment options to emphasize maintenance of normal blood sugar levels.

A program of tight control requires a significant investment of time and effort on the part of the patient and the caregivers, especially critical is patient education, self-monitoring of blood-glucose levels and regular checkups. Interestingly enough, managed care makes it more difficult for a dedicated program of “tight control”.7

**SUMMARY**

It has been said that diabetes is a chronic disease without a cure. It can be a devastating disease to both the patient and the family. It requires a great deal of time, education and finances to properly care for a diabetic patient. Truly, comprehensive pharmaceutical care must incorporate pharmaceutical compounding to meet the individualized needs of patients with diabetes. As no two diabetics are alike, their therapeutic needs are different. Off-the-shelf products don’t address individualized needs and nonavailability of needed preparations can only be met by individual preparations.

**COMPOUNDING INSULIN MIXTURES**

When it is necessary to compound insulin mixtures either by combining different types of insulin or diluting insulin to a lower concentration for use in insulin pumps, the following guidelines should be considered.

1. Regular insulin and NPH insulin can be mixed in any proportion (good for 30 days at room temperature).
2. Lispro insulin and NPH/lente insulin can be mixed (but should be injected immediately).
3. Lente and ultralente insulins may be combined in any ratio (good for 18 months if refrigerated).
4. Novo-Nordisk’s Velosulin contains different buffers and should not be mixed with any lente preparation.
5. Using a dilution fluid to dilute regular insulin for pump use:
   A. When using Lilly’s Insulin Dilution Fluid, the regular insulin can be mixed in any ratio and will be stable indefinitely.
   B. When using 0.9% sodium chloride injection to dilute insulin, it can be mixed in any proportion but should be used within 2-3 hours as there may be a change in pH and buffering that may adversely affect the stability of the insulin.
6. For pump use, Velosulin has an added phosphate buffer system that will minimize or prevent the crystallization of insulin in the tubing of insulin pumps.
7. The new basal insulin glargine, or Lantus, cannot be mixed with other insulins.

**USEFUL FORMULATIONS FOR ORAL ADMINISTRATION**

Rx Sugar-Free Suspension Structured Vehicle, USP

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xanthan gum</td>
<td>200 mg</td>
</tr>
<tr>
<td>Saccharin sodium</td>
<td>200 mg</td>
</tr>
<tr>
<td>Potassium sorbate</td>
<td>150 mg</td>
</tr>
<tr>
<td>Citric acid</td>
<td>100 mg</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>2 g</td>
</tr>
<tr>
<td>Mannitol</td>
<td>2 g</td>
</tr>
<tr>
<td>Glycerin</td>
<td>2 mL</td>
</tr>
<tr>
<td>Purified water</td>
<td>qs 100 mL</td>
</tr>
</tbody>
</table>

1. Accurately weigh/measure each of the ingredients.
2. Using moderate heat, heat 30 mL of purified water in a beaker on a hotplate.
3. Stir to form a vortex and slowly sprinkle the xanthan gum into the vortex.
4. In a separate beaker, dissolve the saccharin sodium, potassium sorbate and citric acid in 50 mL of purified water.
5. Using moderate heat, incorporate the sorbitol, mannitol and glycerin into this mixture and then add to the previously prepared xanthan-gum dispersion.
6. Add sufficient purified water to volume and mix well.
7. Package and label.

(Text continued on fold over page)
1. Accurately weigh/measure each of the ingredients.
2. Mix the parabens and the desired flavor materials with a small quantity of glycerin.
3. Incorporate the sorbitol solution.
4. Add sufficient methylcellulose 2% solution to volume and mix well.
5. Package and label.

**Rx Foot Circulation Gel**

Nifedipine 16 g
Diethylene glycol monoethyl ether 10 mL

**NOTE:** The nifedipine is very light sensitive so work quickly and in subdued light to minimize the exposure of the nifedipine to any light source.

1. Accurately weigh/measure each of the ingredients.
2. Mix the nifedipine with the diethylene glycol monoethyl ether.
3. Add the lecithin:isopropyl palmitate solution and mix well.
4. Add sufficient Pluronic F127 30% gel to volume and mix well using a shearing stress technique.
5. Package and label.

**Rx Lanolin Foot Ointment**

Lanolin 25 g
Aquabase 50 g
Wheat germ oil 10 g
Mineral oil 15 g
Aromatic oil qs (optional)

1. Accurately weigh/measure each of the ingredients.
2. Using low heat (water bath), melt the lanolin.
3. Incorporate the Aquabase, wheat germ oil and mineral oil and mix well.
4. Remove from heat, add the aromatic oil and cool with intermittent stirring.
5. Package and label.

**Rx Foot Cream**

Glycerin 30 g
Purified water 30 g
Methylparaben 200 mg
Propylparaben 100 mg
Mineral oil 9 g
Petrolatum, White 20 g
Glycerol monostearate 3 g
Cetomacrogol 1000 BP 4 g
Lanolin 2 g
Stearyl alcohol 2 g

1. Accurately weigh/measure each of the ingredients.
2. Dissolve the parabens in a heated mixture of the glycerin and the purified water (about 60°C).
3. Heat all the remaining ingredients in a separate beaker to about 60°C. Remove from heat.
4. Add the mixture from step #3 to the solution in step #2 with stirring while cooling.
5. Package and label.

**USEFUL FORMULATIONS FOR FOOT CARE**

**USEFUL FORMULATIONS FOR MAINTAINING SKIN HYDRATION**

**Rx Glycolic Acid 10% Cream**

Glycolic acid 10 g
Dermabase 90 g

1. Accurately weigh/measure each of the ingredients.
2. Mix the glycolic acid with a small quantity of glycerin or propylene glycol until smooth.
3. Incorporate the Dermabase and thoroughly mix.
4. Package and label.

**Rx Lactic Acid 10%, Urea 10%, Glycolic Acid 10% Cream**

Lactic Acid 11.4 mL
Urea 10 g
Glycolic acid 10 g
Dermabase qs

1. Accurately weigh/measure each of the ingredients.
2. Dissolve the lactic acid, urea and glycolic acid in about 15 mL of purified water.
3. Incorporate into the Dermabase and mix well.
4. Package and label.

**USEFUL FORMULATION FOR TREATING DIABETIC NEUROPATHIC PAIN**

**Rx Ketamine HCl, Amitriptyline HCl and Gabapentin in PLO**

Ketamine hydrochloride 5 g
Amitriptyline hydrochloride 2 g
Gabapentin 6 g
Diethylene glycol monoethyl ether 10 mL
Lecithin:isopropyl palmitate solution (1:1) 22 mL
Pluronic F127 30% gel qs

1. Accurately weigh/measure each of the ingredients.
2. Dissolve the parabens in a heated mixture of the glycerin and the purified water (about 60°C).
3. Heat all the remaining ingredients in a separate beaker to about 60°C.
4. Add the mixture from step #3 to the solution in step #2 with stirring while cooling.
5. Package and label.
1. Accurately weigh/measure each of the ingredients.
2. Mix the ketamine hydrochloride, amitriptyline hydrochloride and gabapentin with the diethylene glycol monoethyl ether.
3. Add the lecithin:isopropyl palmitate solution and mix well.
4. Add sufficient Pluronic F127 30% gel to volume and mix well using a shearing stress technique.
5. Package and label.

**USEFUL FORMULATION FOR TREATING DECUBITUS ULCERS**

**Rx Topical Diabetic Skin Ulcer Cream**

- Misoprostol 2.5 mg
- Phenytoin 2 g
- Lidocaine 2 g
- Glycerin qs 5 mL
- Dermabase 100 g

1. Accurately weigh/measure each of the ingredients.
2. Comminute the misoprostol, phenytoin and lidocaine to a fine powder.
3. Add the glycerin and mix to a smooth paste.
4. Add sufficient Dermabase, geometrically, to volume and mix well.
5. Package and label.

**USEFUL FORMULATION FOR TREATING ORAL SORES**

**Rx Oral Sore Mouth Rinse**

- Misoprostol 1 mg
- Lidocaine hydrochloride 500 mg
- Methylparaben 200 mg
- Glycerin 10 mL
- Cherry flavor, anhydrous 1 drop
- Syrup 40 mL
- Sodium carboxymethylcellulose 0.25% solution qs 100 mL

1. Accurately weigh/measure each of the ingredients.
2. Pulverize five of the 200-µg misoprostol tablets.
3. Dissolve the methylparaben in the glycerin and add the lidocaine hydrochloride, pulverized misoprostol tablets and the cherry flavor.
4. Add the syrup and sufficient sodium carboxymethylcellulose 0.25% solution to volume and mix well.
5. Package and label.

**USEFUL FORMULATION FOR GUM DISEASE**

**Rx Chlorhexidine 0.15% Solution**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine digluconate solution</td>
<td>0.75 mL</td>
</tr>
<tr>
<td>Peppermint oil</td>
<td>2-3 drops</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>10 mL</td>
</tr>
<tr>
<td>Sorbitol 70% solution</td>
<td>10 mL</td>
</tr>
<tr>
<td>Aspartame</td>
<td>40 mg</td>
</tr>
<tr>
<td>Purified water</td>
<td>100 mL</td>
</tr>
</tbody>
</table>

1. Accurately weigh/measure each of the ingredients.
2. Add the chlorhexidine digluconate, sorbitol 70% solution and aspartame to about 75 mL of the purified water and stir until dissolved.
3. Separately, mix the peppermint oil with the propylene glycol, then add to the solution in step #2.
4. Add sufficient purified water to make 100 mL and mix well.
5. Package and label.

**USEFUL FORMULATION FOR TREATING OPHTHALMIC DRYNESS**

**Rx Sodium carboxymethylcellulose**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9% Sodium chloride solution</td>
<td>99 g</td>
</tr>
</tbody>
</table>

1. Accurately weigh/measure each of the ingredients.
2. Slowly dissolve the sodium carboxymethylcellulose in the 0.9% sodium chloride solution.
3. Package, autoclave and label.

**REFERENCES**