Basal cell carcinoma, squamous cell carcinoma and malignant melanoma seem to be more and more common. Our goal in this lesson is to discuss the effect of sunlight on the skin. This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-06-008-H01.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

2. Describe the effect of various bands of UVR on the skin & underlying cutaneous tissue.
3. Identify environmental factors that play a role in the amount of UVR that impacts the skin.
4. List the layers of the skin & describe the formation of melanin.
5. Discuss the various types of sunscreens.
6. Comment upon the newest OTC sunscreen that has been approved by the FDA.

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.
In spite of warnings that frequent and prolonged exposure to sunlight is potentially harmful to the skin, sunbathing for the purpose of tanning is a popular outdoor activity that is practiced by a significant number of people. Likewise, occupational exposure to radiation can be hazardous and may lead to skin diseases such as squamous cell carcinoma and basal cell carcinoma. The incidence of malignant melanoma has doubled in the last ten years, probably due to overexposure to sunlight. In addition to the aforementioned diseases, sunlight can cause sunburn, premature aging of the skin, immunologic changes, cataracts, photodermatoses, phototoxicity and photoallergy. Photaging or premature aging of the skin which results from exposure to sunlight is characterized by increased wrinkling, dryness, and thickening that appears yellowish in color. Unlike aging of the skin as a result of natural processes, photoaging causes degenerative, histological, and biochemical reactions that lead to a breakdown of the skin’s elastic tissue. Furthermore, solar keratoses, cracking, spider vessels, and subcutaneous hemorrhaging may occur. Immunologic changes such as photoallergy are due to an increase in the reactivity of the skin to sunlight, which may be caused by an antigen reaction within the skin, resulting in urticaria, blisters, and sunburn. Phototoxicity differs from photoallergy in that it is not due to an immunologic reaction. It may emerge as a sunburn resulting from exposure to a chemical or intake of drugs such as tetracycline, sulfonamide, 5-fluorouracil, a hyperglycemic drug, chlorpromazine, tretinoin, phenytoin or benzyl peroxide. Photodermatoses is characterized by the appearance of erythema and vesicles only on the skin that is exposed to sunlight.

**SUNLIGHT**

The spectrum of UV radiation is divided into three primary bands with different wave lengths: Ultraviolet A (UVA), Ultraviolet B (UVB), and Ultraviolet C (UVC).

**UVA (320-400nm) radiation** is closest in wavelength to visible light and it is the longest and the least harmful of UV radiation bands. However, more UVA reaches the earth’s surface than UVB. It is capable of penetrating the dermal layers of the skin and thus may contribute to mild erythema and other damaging effects to the dermis, causing vascular damage. Even though UVB is the primary cause of premature aging of the skin, it is believed that UVA is also involved in such effects as well as in interfering with the immune system and causing damage to deoxyribonucleic acid (DNA). Thus UVA may augment the damage caused by UVB. Most sensitivity reactions are induced by this band.

**UVB (290-320 nm) radiation** is the most active UV radiation and is responsible for erythrogenic and melanogenic effects. It acts as a contributing factor for causing skin cancer, wrinkles and premature aging. The vast majority of UVB radiation is incapable of penetrating the stratospheric zone layer and is absorbed by the skin. It is about 800-1000 times as intense as UVA. Normal exposure to UVB promotes the synthesis of vitamin D$_3$ in the skin. Elderly individuals who are bedridden as well as infants and persons deprived of direct sunlight may require the intake of vitamin D supplements. UVB is considered the main reason for photoaging (wrinkling, epidermal hyperkeratosis, elastosis, and collagen breakdown) as well as skin cancer. Overexposure to UVB can lead to eye problems such as cataracts. A large segment of the population wrongly believes that ordinary sunglasses can filter out UVB.

**UVC (200-290 nm) radiation**, known as germicidal radiation, causes more damage to the skin, but less tanning than either UVA or UVB. However, such rays are absorbed completely by the stratospheric ozone-layer, and very small amounts of this radiation reach earth, causing little damage to the skin. Artificial UV sources such as those used during the manufacture of sterile products produce UVC. Exposure to such radiation may cause irritation, cataracts, and burns of various degrees.

**ENVIRONMENTAL FACTORS**

The ozone layer that surrounds the earth plays an important role in filtering and reducing the amount of ultraviolet radiation (UVR) that reaches the earth’s surface from the sun. In the last 25 years it has been concluded that a reduction in the amount of ozone layers that shield the earth has taken place. It has been reported that chlorofluorcarbons (CFC6) that are used as refrigerants and as propellants in aerosols as well as pollutants such as nitrous oxide released from jet aircrafts,
Melanin is an insoluble brown-black pigment that provides color to the skin, hair, substantia nigra, and choroid of the eyes. Melanin is synthesized by the melanocytes that are distributed in the stratum germinativum. These melanin forming cells have long branching tubes (dendrite cells) through which the melanin is injected into the neighboring nonmelanin forming cells of the stratum germinativum. The increase in number of new cells, formed in the stratum germinativum, causes gradual thickening of the skin. The stratum germinativum contain melanocytes, which are the melanin-forming cells. The dermis, which makes up the bulk of the skin, is composed mainly of collagen and elastic fibrous elements that give the skin its toughness and elasticity. Within the dermis are blood vessels, lymphatics, nerves, sebaceous and sweat glands and hair follicles. The subcutaneous tissue, or hypodermis, consists of loose connective tissue that contains lipocytes that forms and stores fat within this area of the skin. The subcutaneous tissue serves as a heat insulator, external shock absorber, and the reserve depot of fat. Dieting results in wrinkles in the skin due to consumption of the fatty tissue and the failure of the skin to shrink at the same time.

The skin is the largest organ, and separates the internal organs from the external environment. It acts as a protective covering of the underlying tissue and serves as an organ of sensation, excretion, and body temperature control. The skin is divided into three major parts: the epidermis, the dermis, and the subcutaneous tissue.

The epidermis is the outermost part of the skin and consists of several layers. Beginning from the exterior, the layers are the stratum corneum, the stratum granulosum, the prickle cells, and the stratum germinativum. The stratum corneum is composed of keratinized dead cells that are instantly being shed from the surface and replaced by newer cells, generated by the stratum germinativum. As these cells leave the stratum germinativum they push the older cells upward toward the skin surface where they become dry, keratinized and gradually die. Thickening of the stratum corneum is normally a defense mechanism which may follow a surface trauma such as friction, pressure, heat, or sunlight. Beneath the stratum corneum is the stratum granulosum which consists of flattened granular cells containing keratohyalin, a compound converted to keratin as it reaches the skin surface. The prickle cells are cytoplasmic bridges between the cells, and appear prominently above the stratum germinativum. The stratum germinativum is mitotically active and is the source of the newly formed cells. The aforementioned layers of the skin are reflections of the stages that the newly formed cells pass through in their gradual conversion into keratinized dead cells. The stratum germinativum contain melanocytes, which are the melanin-forming cells.

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The precursor of the synthesis of melanin is the amino acid tyrosine. The enzyme tyrosinase oxidizes tyrosine to dihydroxyphenylalanine (dopa). A series of reactions occur, which finally result in the formation of melanin. Stimulation of tyrosinase to act on tyrosine to start melanin synthesis can be accomplished by UV radiation or exposure to sunlight. Melanin synthesis by melanocytes is regulated by the melanocyte-stimulating hormone (MSH), which is secreted by the anterior pituitary gland. Hormones of the adrenal cortex antagonize the effects of MSH, and consequently a balance is established for the control of melanin production. Absence or diminished secretion of adrenocortical hormones, as in Addison’s disease, causes MSH to predominate, leading to darkening or tanning of the skin.

ACUTE AND CHRONIC EFFECT OF SUNLIGHT

Sunbathing and other outdoor activities are common during warm weather. Some individuals tend to sunbathe regularly, while others perform such activity occasionally, particularly while on vacation. In some occupations, exposure to sunlight is inevitable. Overexposure to UV radiation may cause acute or chronic reactions of the skin.

Acute reactions are manifested as sunburn, an inflammation of the skin caused by excessive exposure or hypersensitivity to UV radiation or to any actinic sources. Exposure to sunlight for short durations may result in mild irritation with subsequent drying and scaling of the skin. Repeated prolonged exposure, as often happens with vacationers who attempt to acquire a tan very quickly, may result in moderate to severe acute reaction. The affected area becomes red, hot, tender, and swollen. Blisters may form. Involvement of large areas of body surface may result in fever, headache and discomfort. Shock may occur due to elevation of body temperature by sun, heat, or heat exhaustion. The symptoms usually appear within 6 to 24 hours following exposure to sunlight, and begin to subside within 48 to 72 hours. Stimulation of the production of both keratin and melanin occurs to protect the underlying tissues. The quick tanning is due to oxidation of colorless melanin present in the reduced state. This process differs from the normal production of new melanin in the skin. The severity of the acute reaction to sunlight depends on the type of the skin, the measures taken to protect the skin, duration of exposure, and
the intensity of the UV radiation. An increase in the reactivity of UV radiation may occur in certain individuals who are taking potentially photosynthesizing drugs such as the chlorothiazides, sulfa drugs, phenothiazines, sulfonylureas, hypoglycemics, griseofulvin, nalidixic acid and tetracyclines (especially demeclocycline). The UV rays react with a drug to produce a toxic drug form that triggers an exaggerated sunburn-like reaction within several minutes of exposure to the sun or any source of UV radiation.

**Chronic reactions** to sunlight may accelerate the aging process of the skin, and may contribute to acute keratosis and cancer of the skin. Repeated sunburn and/or regular over exposure to sunlight or the indiscriminate use of UV lamps over many years may result in degenerative changes in the skin and often leads to premature aging. Both the elastic fibrous elements and collagen of the dermis as well as the fat of the subcutaneous tissue may breakdown, resulting in thinning, sagging, furrowing, wrinkling, and yellowing of the skin. The epidermis becomes dry and may show premalignant actinic (solar) keratosis (commonly called senile keratosis), basal cell carcinoma, squamous cell carcinoma and malignant melanoma. Actinic keratoses are slightly elevated, rough, hard, grayish to dark patches of keratotic skin. They are usually multiple and range from 2 mm to one centimeter in diameter. Even though actinic keratosis occurs predominantly in individuals 40 years of age or older, aging is not the primary cause. The effect of sunlight is evident since such lesion development occurs only on areas of the skin that have received excessive amounts of UV radiation. Contrariwise, unexposed areas of the skin appear normal. Premature aging of the skin in the development of actinic keratosis is seen in farmers, outdoor sports persons, sailors, and regular sunbathers.

Basal cell carcinoma is the most common type of skin cancer, and usually is encountered on the head, face (especially around the eyes and nose), or hands. It is most often seen among middle aged or elderly, light-skinned persons. The initial lesion develops as a small papule that increases in size gradually and appears as a pale, waxy nodule with a center ulcer. Squamous cell carcinoma originates from the prickle cells. The lesion appears as a hard nodule which after a period of months or years begins to grow in size and becomes ulcerative. The lips, hands, and ears are the most common sites. Both basal cell and squamous cell carcinomas do not generally metastasize, but metastases may occur if left untreated.

Malignant melanoma is the most dangerous of the three types of skin cancer because it often metastasizes relatively quickly. It arises from melanin producing cells, which may develop in a mole present since childhood, in a new mole that appears after adolescence, or in a pigmented area of ordinary skin.

**SUNSCREENS**

Sunscreens are agents that either absorb or deflect the vast majority of UV radiation, thereby reducing the damaging effects of the sun and facilitating gradual tanning. The food and drug administration (FDA) review panel classified sunscreens into the following groups:

1. Sunburn preventing agents are chemicals capable of absorbing 95% of UV rays in the 290-320nm range.
2. Suntanning agents absorb 85% of the UV rays from 290-320 nm and promote slow tanning.
3. Opaque agents reflect UV radiation in the range of 290-760nm.

The first and second classes are chemical barrier sunscreens, while the third one is a physical barrier sunscreen. The FDA advising review panel has recommended that the following examples of sunscreens are safe and effective.

**CHEMICAL BARRIER SUNSCREENS**

1. Amino benzoic acid (ABA) or para-amino benzoic acid (PABA) 2-5% and its esters, glycercyl ABA 2-3%, padimate A (amylidimethyl PABA) 1-5%, and padimate o (octyl dimethyl PABA) 1.4-8% are effective sunscreens. The efficacy of ABA is enhanced when prepared with 50-70% ethanol, because such vehicle allows better penetration of the chemical into the epidermis. However, hydroalcoholic vehicles are removed easily as a result of swimming or perspiration. Creams have the ability to remain on the skin for longer periods and tend to keep the skin moist. Amino benzoic acid has low incidence of adverse reactions. Individuals who are allergic to sulfonamides, thiazides, benzocaine and procaine may experience hypersensitivity to ABA. Furthermore, products containing ABA stain clothing yellow. Esters of ABA have a higher incidence of adverse reactions, but cause no staining to clothing. To achieve maximum effect, these preparations should be applied at least two hours prior to exposure to allow penetration of the chemicals into the epidermis.
2. The benzophenones (dioxylbenzones 3%, oxybenzone 2-6%, and sulisobenzone 3-5%) are capable of absorbing UV radiation ranging from 320-400nm. Because of such broad-spectrum activity, these compounds are used in combination with other sunscreens to provide protection against sunburn as well as phototoxicity and photosensitivity.
3. The cinnamates (cinoxate 1-3%, ethylhexyl-o-methoxycinnamate 2-7.5%, and diethanolamine p-methoxycinnamate 8-10%) are not as effective as ABA and wash off from skin easily.
4. The salicylates (homosalate 4-15%, octyl salicylate 3-5% and 2-ethylhexyl salicylate 3-5%) provide less protection against UV radiation than ABA and do not adhere well to the skin.
5. Methyl anthranilate absorbs UVA radiation, but very little UVB radiation. Because of this property, it is included in other sunscreens to broaden the spectrum of activity.

**PHYSICAL BARRIER SUNSCREENS**

Chemicals such as red petrolatum, titanium dioxide and zinc oxide are opaque and act physically by preventing UV rays from reaching the skin. Because of this opacity, these agents do not promote tanning and are not cosmetically acceptable for application to large surfaces of the body.

**SUN PROTECTIVE FACTOR (SPF)**

The vast majority of sunscreen labels contain a numerical value known as the sun protective factor (SPF). This number is of importance since it indicates the efficacy of the product in protecting the skin of the average individual from sunburn. To determine the SPF of a sunscreen the value of the minimal erythema dose (MED) in protected skin with a specific product is divided by the MED in unprotected skin. The MED is defined as the least amount of UV radiation required to cause a minimally perceptible erythema response.

\[
\text{SPF} = \frac{\text{MED in Protected Skin with a Specific Sunscreen}}{\text{MED in Unprotected Skin}}
\]

The SPF indicates the efficacy of a sunscreen as well as length of protected exposure time the product will allow before sunburn occurs. The higher the SPF the more protection is provided by the sunscreen. For example, a sunscreen with an SPF of 10 will permit a person to remain in the sun 10 times longer without sun burning with the sunscreen than without it. Thus, a person who sunburns in half an hour without sunscreen may be able to stay in the sun for five hours with sunscreen before experiencing sun burn. The skin type and responsiveness in the sun will determine what SPF number a product should have in order to provide adequate protection to the user. The following are SPF values that should be followed in the selection of a sunscreen that properly conforms to the user’s skin type:

1. SPF 8-15 should be recommended for individuals of the skin type I (always burns easily, but never tans)
2. SPF 6-7 should be recommended for individuals with skin type II (always burns easily, but tans minimally).
3. SPF 4-5 should be recommended for individuals of the skin type III (burns moderately and tans gradually).
4. SPF 2-3 should be recommended for individuals with the skin type IV (burns easily and tans well).
5. SPF 2 should be recommended for individuals with the skin type V (rarely burns but tans profusely).
6. No SPF is indicated for skin type VI (deeply pigmented).

**ROLE OF THE PHARMACIST IN COUNSELING SUNSCREEN USERS**

The public is becoming more aware of the hazards of excessive exposure to sunlight. Fear of cancer and wrinkling caused many to change their sun tanning habits. Even though a larger number of consumers use sunscreens, it is essential that the pharmacist counsel these individuals as well as others who tend to neglect the use of sunscreens during the sun tanning process on the importance and proper application of sunscreens.

Light-skinned individuals are more likely to become sunburned than persons with a darker skin due to the lower melanin level in the epidermis. The application of sunscreen ointments, creams, or lotions on the exposed parts of the skin may minimize the risk of immediate and long term hazards of UV radiation, and may allow gradual tanning. Additionally, sunburns may be minimized or avoided by taking certain precautionary measures. It is unwise to acquire a tan too quickly. The initial exposure to bright sunlight should be limited to 20-30 minutes. This should be increased by 30 minutes each day until tanning, which offers sun protection, occurs. It must be remembered that throughout this early period, sunscreens having high SPF should be applied. Once a tan is developed, the sunbather may use a sunscreen with a lesser SPF. Since thickening of the keratin is a natural defense mechanism against sunlight, peeling of the skin removes such protection. The use of a sunscreen with a high SPF is recommended until peeling ceases and tanning develops. Sunbathing should be avoided between 11:00 AM and 4:00 PM, when the sunburn-producing wave lengths are at their peak. If erythema occurs, the sunbather should refrain from further exposure until such reaction has subsided. Wearing clothing and hats is helpful in minimizing sunburns of the trunk and face. Application of physical barrier sunscreens to the nose, ears and lips is recommended. Chapsticks containing chemical sunscreen with various SPF’s may be used.

The public should realize that one can become sunburned without exposing the skin to the blazing sun. Sunburns may occur on an overcast or cloudy day because UV rays are capable of penetrating a hazy atmosphere in which one may feel comfortable and secure. Ultraviolet rays can be reflected off surfaces such as snow, sand and water. Since cold temperatures do not block UV penetration, and snow reflects them, one can become sunburned on a skiing vacation. Likewise, a summer vacationer sitting under a beach umbrella may get sunburn.

The proper use of sunscreens should be fully explained to consumers. Chemical barrier sunscreens should be applied approximately 2 hours prior to sunbathing in order to allow the chemicals to bind with the epidermis. The sunscreen should
be applied liberally to all areas of the body that are expected to be exposed to the sun. Swimming and excessive perspiration will cause most sunscreens to wash off. Frequent reapplication and the use of adequate amounts of sunscreen are essential for achieving maximum effectiveness. Consumers should follow the directions and precautions stated on the label of the product. Users should discontinue the use of a sunscreen if irritation appears on the skin. Contact with the eyes should be avoided.

NEW SUNSCREEN

On July 26, 2006, the FDA released the following Press Release, announcing a new OTC Sunscreen Product. In a future lesson, we will discuss this new molecular entity.

FDA News

FOR IMMEDIATE RELEASE
P06-103
July 24, 2006

FDA Approves a New Over-the-Counter Sunscreen Product

The Food and Drug Administration (FDA) today approved Anthelios SX, a sunscreen from L’Oreal to be sold over-the-counter (OTC) for the prevention of sunburn and for protection against ultraviolet B (UVB) and ultraviolet A (UVA) rays. It has a sun protection factor (SPF) of 15.

“Sunscreens are an important part of total sun protection strategy as consumers arm themselves against the harmful sun rays,” said Steven Galson, M.D., Director of the Center for Drug Evaluation and Research. “While this product provides protection from harmful UVA and UVB rays, FDA continues to recommend that in addition to using a sunscreen, consumers protect themselves from sun exposure by limiting time in the sun and wearing protective clothing.”

Anthelios SX is a sunscreen product that contains a combination of three active ingredients. One of the ingredients is a new molecular entity (NME), ecamsule. Ecamsule has not been marketed in the United States, but has been marketed in Europe and Canada as Mexoryl SX since 1993. The other two active ingredients, avobenzone and octocrylene, are generally recognized as safe and effective under the current OTC monograph for sunscreens.

The safety and efficacy data for Anthelios SX included information from 28 studies in over 2500 patients, ranging in age from 6 months to over 65 years old. In addition, the contribution of each of the active ingredients to sun protection was studied. Side effects reported during clinical studies were infrequent and non-serious. The most common side effects in patients were acne, dermatitis, dry skin, eczema, abnormal redness, itching, skin discomfort and sunburn.

REFERENCES
Fill in the information below, answer questions and return Quiz Only for certification of participation to:
CE PRN®, 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.

NAME________________________________________________________________(ID # 1st line on label)____________________________
ADDRESS__________________________________________________CITY_________________________STATE______ZIP_____________
CHECK IF NEW ADDRESS ❑ ARE YOU LICENSED IN FLORIDA? IF YES FL LIC ________________
EMAIL Address (we need this)_________________________________________________________________________

LESSON EVALUATION
Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives? ________________________________
   - Classify ultraviolet bands of radiation ________________________________
   - Describe effect of UVR bands on skin & cutaneous tissue ________________________________
   - Identify environmental factors that play a role in the amount of UVR impacting the skin ________________________________
   - List the layers of the skin & describe formation of melanin ________________________________
   - Discuss the various types of sunscreens ________________________________
   - Comment upon the newest OTC sunscreen that has been FDA approved ________________________________

2. Was the program independent & non-commercial? ________________________________
   - Poor             Average          Excellent

3. Relevance of topic to your practice ________________________________
   - 1 2 3 4 5 6 7

4. What did you like most about this lesson?__________________________________________

5. What did you like least about this lesson?__________________________________________

(WATCH OUR WEBSITE FOR RESULTS OF PARTICIPANT EVALUATIONS)

Quiz—Please Select the Most Correct Answer

1. Which of these is NOT a characteristic of photoaging of the skin?
   A. Increased wrinkling  B. Dryness  C. Oozing  D. Change to yellowish color

2. UVB has a wavelength of 320-400nm.
   A. True  B. False

3. Which of these has a harmful effect on the amount of ozone layers?
   A. Chlorofluorocarbons  B. Moisture  C. Clouds  D. Dust

4. Quick tanning occurs due to:
   A. Dilation of blood vessels  B. Increased keratinization rate  C. Elevation of body temperature  D. Oxidation of colorless melanin present in reduced state

5. Which of these is not a photosensitizing drug?
   A. Chlorothiazide  B. Aspirin  C. Phenothiazine  D. Demeclocycline

6. Melanocytes are found in the:
   A. Stratum corneum  B. Stratum granulosum  C. Dermis  D. Stratum germinativum

7. Actinic keratosis lesions are elevated, rough, hard, & dark patches on the skin.
   A. True  B. False

8. Titanium oxide is a sunscreen that:
   A. Is a physical barrier to sunlight  B. Acts by deflecting sunlight  C. Acts by absorbing sunlight  D. Acts by neutralizing sunlight

9. SPF is recommended to individuals with skin of which type?
   A. Type I  B. Type IV  C. Type V  D. Type VI

10. Chemical barrier sunscreens should be applied:
    A. 5 hours before sunbathing  B. 2 hours before sunbathing  C. In very small quantities  D. 1 hour after sunbathing
Contributing Authors

Farid Sadik, Dean Emeritus
University of South Carolina College of Pharmacy
Columbia, SC

William J. Feinberg,
BS Pharm, MBA

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Pharmacists completing this course by August 31, 2009 may receive full credit. This program has been approved by the State Boards of Pharmacy in Alabama and Oklahoma.

This lesson furnishes 1.25 hours (0.125 CEUs) of credit.

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