

Sun Damage



Have years
in the sun
caused you
to develop
actinic
keratoses?



Please see inside back panel
for brief prescribing information.

Brought to you by ICN Pharmaceuticals, Inc., maker of

EFUDEX[®]
fluorouracil 5% cream

What are actinic keratoses?

Actinic keratoses (AKs) are precancerous lesions that appear on sun-exposed areas of the skin such as the face, ears, arms, legs, hands, and bald scalp. Those who have AKs sometimes have 3 to 10 times as many subclinical lesions (AKs that are underneath the skin's surface and are not yet visible) as they do visible ones. AKs can be flesh-colored, tan, red, or brown and as small as a fraction of an inch. When they first appear, they are usually smooth and flat. Over time, they multiply and form larger patches that may feel scaly and rough to the touch—similar to the way sandpaper feels. Some people complain that these lesions burn or sting.

AKs are the cumulative result of years of sun damage, which is why so many older people have them. Even if you have been scrupulous about sun protection in the recent past, you are still at risk if you spent time in the sun when you were younger. Young people are also not immune, especially if they spend a great deal of time working or playing outdoors.

Many doctors now believe that an AK is the first sign of skin cancer. Left untreated, these precancerous lesions could present more serious problems, which we will discuss later in this brochure. If you suspect you have AKs, talk to your doctor. Only your doctor can diagnose and treat these precancerous lesions.

Who is at risk for developing AKs?

If you have spent a great deal of time outdoors without sun protection, you're at risk for developing AKs. This is especially true if you have a fair complexion, blond or red hair, and light-colored eyes. Men develop AKs more often than women. This may be due to the fact that many men work or have hobbies that cause them to spend more time outdoors. If they're not wearing sun protection, in time they'll see how the "great outdoors" is not so great for their skin.

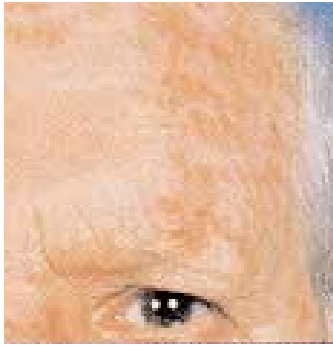
How can I check to see if I have AKs?

Look at yourself in a mirror. AKs are most likely to form on areas of your skin that are frequently exposed to direct sunlight such as your face, ears, hands, arms, legs, or bald areas of your scalp. First appearing as small tan, brown, or reddish-brown patches, AKs can range from a few millimeters to a few centimeters in diameter. These lesions may be flat or raised and generally have ill-defined or irregular borders.

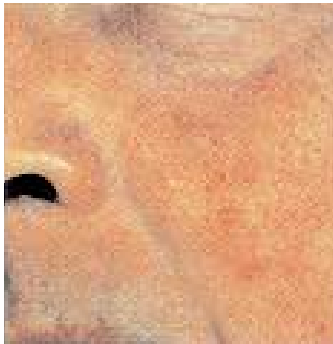
Feel any lesions you may have that fit this description. Typically, AKs will have a white scaly top and will be rough and gritty to the touch. Some may form a hard, depressed scar-like mass. If you have any lesions that fit this description, or questions regarding AKs, please talk to your doctor.



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describing AKs which might
be found on the face or
hands*



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describing AKs which might
be found on the face or
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be found on the face or
hands*



Hand or arm
lesion art
to come

*caption copy goes here
describing AKs which might
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hands*

What could happen if my AKs aren't treated?

AKs consist of atypical squamous (scaly) cells that are precancerous and confined to the outermost layer of the skin, which is called the epidermis. When left untreated, AKs can evolve and penetrate into the next layer of skin (the dermis), which would indicate the development of squamous cell carcinoma (SCC), a curable form of skin cancer. Up to 60% of SCCs develop from actinic keratoses.¹ While SCCs that evolve from AKs are not aggressive, they may eventually metastasize (spread) to other organs.² This is why treating AKs is highly recommended.

Actinic cheilitis, a particularly aggressive type of AK that develops on the lips, sometimes transforms into a type of SCC that can spread rapidly to other parts of the body.

How are AKs treated?

If you have a few isolated AKs, your doctor will probably freeze the lesions using liquid nitrogen. This spot treatment is called cryosurgery and is very successful. But when there are numerous AKs, topical 5-fluorouracil (5-FU) is recommended. In addition to treating visible AKs, 5-FU has the additional advantage of seeking out those AKs that are not yet visible to the naked eye—the subclinical lesions we mentioned earlier. The most commonly prescribed brand, one that doctors have trusted for the past 35 years, is EFUDEX® (fluorouracil). If your doctor does diagnose you with AKs, ask if EFUDEX® is right for you.

EFUDEX[®] fluorouracil

TOPICAL SOLUTIONS AND CREAM

For Topical Dermatological Use Only—Not for Ophthalmic Use

Before prescribing, please consult complete product information, a summary of which follows:

INDICATIONS

Multiple actinic or solar keratoses. In 5% strength, useful in the treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites. Establish diagnosis before treating, as this method has not been proven effective in other types of basal cell carcinomas. Surgery is preferred for isolated, easily accessible lesions, as success rate is nearly 100%. Success rate with Efudex is about 93%.

CONTRAINDICATIONS

May cause fetal harm. Contraindicated in women who are or may become pregnant during therapy. Contraindicated in patients with known hypersensitivity to any of its components.

WARNINGS

Application to mucous membranes should be avoided due to the possibility of local inflammation, ulceration and vaginal necrosis. If occlusive dressing is used, may increase inflammatory reactions in adjacent normal skin. Avoid prolonged exposure to ultraviolet rays because the intensity of the reaction may be increased.

PRECAUTIONS

Possibility of increased absorption through ulcerated or inflamed skin. Warn patients that treated area may be unsightly during therapy and sometimes for several weeks after. If applied with fingers, wash hands immediately. Apply with care near eyes, nose and mouth. Do not apply intravaginally. Solar keratoses failing to respond should be biopsied. Perform follow-up biopsies in superficial basal cell carcinoma. There have been no long term studies to evaluate carcinogenic potential. 5-fluorouracil in vitro studies have shown positive effects for mutagenicity and impairment of fertility. Nursing Mothers: It is not known whether Efudex is excreted in human milk. Pediatric Use: Safety and efficacy in children have not been established. Geriatric Use: There are no adequate and well-controlled studies exclusively in geriatric patients.

ADVERSE REACTIONS

Burning, crusting, allergic contact dermatitis, erosions, erythema, hyperpigmentation, irritation, pain, photosensitivity, pruritus, scarring, rash, soreness and ulceration at application site are most frequent. Also, vaginal necrosis, ulcerations and other local reactions, cases of miscarriage and a birth defect have been reported when Efudex was applied to mucous membrane areas. Leukocytosis is the most frequent hematological side effect. There have been other adverse reactions infrequently reported in the central nervous system, gastrointestinal, hematological, integumentary, as well as special senses and miscellaneous categories.

DOSAGE AND ADMINISTRATION

When Efudex is applied, erythema occurs, then vesiculation, desquamation, erosion, and reepithelialization. Actinic or Solar Keratosis – apply sufficient quantity to cover lesions, twice daily. Usual length of therapy is 2 to 4 weeks. Superficial Basal Cell Carcinomas – apply sufficient quantity (only 5% strength recommended) to cover lesions, twice daily. Continue treatment for at least 3 to 6 weeks, but possibly as long as 10 to 12 weeks.

HOW SUPPLIED

Solutions, 10-mL drop dispensers containing 2% or 5% fluorouracil on a weight/weight basis. Cream, 25-gm tubes containing 5% fluorouracil in a vanishing cream base.

What can I do to prevent AKs?

- 1 Avoid unprotected exposure to the sun, especially during the hours of 10 AM to 4 PM when its rays are strongest.
- 2 Wear protective clothing including a hat with a wide brim.
- 3 Always use sunscreen with a sun protection factor (SPF) of at least 15.
- 4 Avoid tanning salons and artificial tanning devices. If you can't bear a summer without a tan, consider using a cosmetic self-tanning lotion.
- 5 Regularly examine your skin, and report any changes or suspicious spots to your doctor.

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**To learn more about AKs and skin cancer,
you may want to contact the following
nonprofit organizations:**

The Skin Cancer Foundation

www.skincancer.org

1-800-SKIN-490

The American Academy of Dermatology

www.aad.org

1-888-462-DERM

**The National Skin Cancer Prevention
Education Program**

*A Division of The Centers for Disease Control
and Prevention*

www.cdc.gov/cancer/nscpep

1-888-842-6355

The American Cancer Society

www.cancer.org

1-800-ACS-2345

1. Marks R, Rennie G, Selwood TS. Malignant transformation of solar keratoses to squamous cell carcinoma. *Lancet*. 1988;1:795-797.
2. Moller R, Reymann F, Hou-Jensen K. Metastases in dermatological patients with squamous cell carcinoma. *Arch Dermatol*. 1979;115:703-705.



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