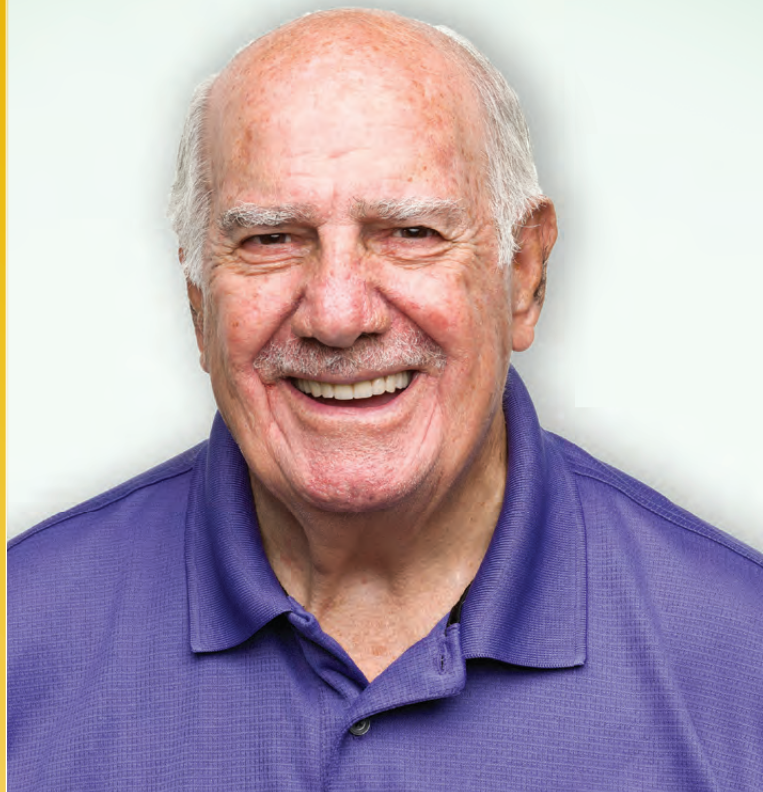


Treatment with Efudix®

Answers to your
questions.



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Efudix® is proudly marketed by



Radiant Health

Topical Cream
EFUDIX®
fluorouracil



Questions you may ask about Efudix®.

1. Why did my doctor prescribe EFUDIX®?

Your doctor prescribed EFUDIX® (flourouracil) because you have been diagnosed with a skin disease called actinic keratoses (AKs), (also known as “solar keratoses”) and/or Bowen’s disease, (also known as “squamous cell carcinoma-in-situ” or “intraepidermal squamous cell carcinoma (SCC)”). These precancerous skin lesions are the result of years of unprotected exposure to the sun’s ultraviolet (UV) rays. Even if you have been extra careful about sun protection in the recent past, if you spent time in the sun when you were younger, you may have put yourself at risk of developing AKs and/or Bowen’s disease.

2. What should I know about AKs?

AKs first appear as small tan, brown, or reddish-brown patches. They can be as small as a few millimetres, be flat or raised, and have a white scaly top that’s rough to touch. People can have 3 to 10 times as many subclinical lesions (AKs that are under the skin’s surface and are not yet visible) as they do visible ones.¹ Over time, AKs multiply and form larger patches on parts of the skin that are exposed to the sun (e.g. face, ears, bald scalp, hands, arms, and legs). Left untreated, a very small percentage of these

precancerous skin lesions can develop into squamous cell carcinoma (SCC), a dangerous form of skin cancer that can spread to other parts of your body.

3. What should I know about Bowen’s disease?

Bowen’s disease appears as dull red, sharply defined, round to oval, raised, crusted and scaling patches and plaques. Typically appears in patients over 60 years of age. Lesions are most commonly located on sun-exposed areas (e.g. head, arms, neck, trunk and legs).

4. How does EFUDIX® work?

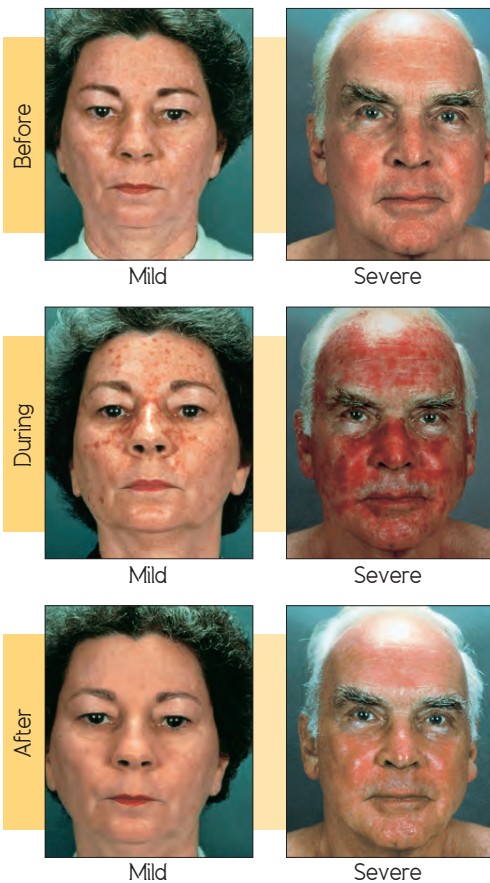
It is believed that the active ingredient (flourouracil) in EFUDIX® interferes with a cell’s ability to reproduce. The precancerous skin cells multiply more frequently than normal cells. As a result, they absorb the medicine (EFUDIX®) faster than the surrounding healthy cells. This is how EFUDIX® can destroy the abnormal cells while having less effect on healthy normal cells.²⁻⁵

Questions you may ask about Efudix®.

5. What can I expect during treatment?

During treatment, the areas of your skin that have AKs and/or Bowen's disease will probably look and feel irritated. This is typical and should not cause you any concern.

The Course of Treatment -
Reactions vary from patient to patient



The redness, crusting, and peeling you see are signs that EFUDIX® is working to eliminate the abnormal cells. While you may find this stage of treatment to be unattractive and somewhat uncomfortable, it is important that you **DO NOT STOP THERAPY** without first obtaining your doctor's approval.

You may also find that areas of your skin where there were no lesions may also become red and inflamed. That's because abnormal cells can become inflamed even if the cells were not previously noticeable on the skin's surface.⁶⁻⁸ As a result, the more abnormal skin cells you have, the more redness and inflammation you can expect during treatment with EFUDIX®.

6. How do I use EFUDIX® ?

If you have been prescribed EFUDIX® for AKs, you need to apply it as directed by your Doctor. This is typically once or twice a day; in the morning and/or evening, but not at bedtime as contact with pillows may cause undesirable spreading. If you were prescribed EFUDIX® for Bowen's disease, your doctor will give you specific instructions. Use enough cream to cover the lesions, and be careful when applying near the eyes, nose, and mouth. You may apply EFUDIX® with your finger, a non-metal applicator or a rubber glove. Be sure to wash your hands thoroughly after each application.

Questions you may ask about Efudix®.

7. Are there people who should not use EFUDIX®?

EFUDIX® is contraindicated (should not be used) in women who are or may become pregnant during therapy because it may cause harm to the foetus. If you are nursing, be sure to let your doctor know because it is not known whether EFUDIX® is excreted in human milk. EFUDIX® is also contraindicated in patients with a known hypersensitivity (known to be allergic) to any of its components.

8. Should I avoid the sun while using EFUDIX®?

You should avoid sun exposure or other UV light (such as tanning booths) during and immediately following treatment with EFUDIX® because the intensity of the reaction may be increased. After your treatment with EFUDIX® is completed, be sure to use sunscreen on a daily basis to protect your skin from future exposure to ultraviolet light.

9. How can I tell the difference between a normal reaction to EFUDIX® and an allergic reaction?

If you have any concerns or questions about your reaction to EFUDIX®, talk to your doctor. Your doctor can best assess whether your reaction to EFUDIX® is normal or an allergic response.

10. How long will I have to use EFUDIX®?

Patients being treated for AKs typically use EFUDIX® once or twice a day for 3 to 4 weeks. If you are being treated for Bowen's disease, your doctor will advise you how long to use EFUDIX®.

11. What can I do to cope with the inflammation associated with EFUDIX®?

Talk to your doctor; he/she can best advise you.

12. Can I wear cosmetics or use moisturisers while using EFUDIX®?

Unless instructed by your doctor, it is advised not to use cosmetics or any other skin products, including creams, lotions, and medications, while on EFUDIX® therapy.

13. What should I do if I forget to use EFUDIX®?

If you forget to use EFUDIX® one day, simply resume using it as prescribed by your doctor. Do not increase or double your dose.

Questions you may ask about Efudix®.

14. How long after EFUDIX® therapy will my skin look irritated?

This can vary depending on the number of AKs and/or Bowen's disease lesions you have and the duration of your EFUDIX® therapy. Generally speaking, your skin will begin to return to normal within 2 to 4 weeks of completing therapy.⁹ However, in some instances, this process takes a little longer.

15. I noticed some spots on my legs that I forgot to show my doctor. Can I use EFUDIX® here too?

Only your doctor can determine if the "spots" you have are AKs and/or Bowen's disease. This is why it is so important to use EFUDIX® only as directed and discuss any questions you may have with your doctor.

16. What should I do with any EFUDIX® that is left over after I complete therapy?

Ask your pharmacist to discard any unused portion of EFUDIX® after you have completed therapy. Do not share your EFUDIX® with anyone else.

17. What kind of follow-up care is needed?

Your doctor will want to see you throughout and/or after therapy, to assess how you are healing. A few follow-up visits may be necessary, but this is best left to the discretion of your doctor. It is important to attend these follow-up appointments.

18. Are there any other things I need to know about EFUDIX® therapy?

- Do not cover the treated areas with bandages or gauze unless your doctor advises you to do so.
- Do not share this medication with others, even if they seem to have the same condition as you.
- The most frequent side effects of EFUDIX® occur locally and may include itching, burning, soreness, tenderness, scaling, and swelling. If any of these side effects are of concern to you, please contact your doctor.
- Application to mucous membranes (e.g. mouth, eyes, vagina, anus) should be avoided due to the possibility of local irritation.

Remember – keep your follow-up appointment with your doctor.

Doctor's details:

Special Instructions just for you:

DO NOT USE IF YOU ARE PREGNANT. The active ingredient in EFUDIX® may be absorbed through the skin and mucous membranes (e.g. mouth, eyes, vagina, anus) and may cause birth defects. If you become pregnant during therapy, stop using EFUDIX® immediately and inform your doctor.

References: **1.** Abel EA, *et al.* When actinic keratoses are a problem. *Patient Care.* 1992;26:115-133. **2.** Maddin S. Dermatologic therapy. In: Moschella SL and Hurley HJ, eds: *Dermatology.* 2nd ed. Philadelphia, Pa: WB Saunders Co;1985:1946-1979. **3.** Simmonds WL. Management of actinic keratoses with topical 5-fluorouracil. *Cutis.* 1976;18:298-300. **4.** Sturm HM, *et al.* Treatment of actinic keratoses with topical 5-fluorouracil. *J Med Assoc Ga.* 1968;(suppl 7):205-209. **5.** Eaglstein WH, *et al.* Fluorouracil: mechanism of action in human skin and actinic keratoses. I. Effect on DNA synthesis *in vivo.* *Arch Dermatol.* 1970;101(2):132-139. **6.** Belisario JC. Topical cytotoxic therapy of solar keratoses with 5-fluorouracil. *Med J Aust.* 1969;2(23):1136-1140. **7.** Arnold HL, *et al.* *Andrews' Diseases of the Skin.* 8th ed. Philadelphia, Pa: WB Saunders Co;1990:754-756. **8.** Willis I. Photosensitivity and phototherapy. In: Moschella SL and Hurley HJ, eds: *Dermatology.* 2nd ed. Philadelphia, Pa: WB Saunders Co;1985:389-424. **9.** Edward WB *et al.* New Approaches to the Treatment of Actinic Keratoses. *Am J Cancer* 2003; 2(3):151-168. EFUDIX - Fluorouracil 5% Cream is a fully funded Prescription Medicine. Please refer to the Consumer Medicine Information on www.medsafe.govt.nz Additional information on Efudix can be obtained from the Valeant Pharmaceuticals New Zealand Ltd. C/O Supply Chain Solutions, 74 Westney Road, Airport Oaks, AUCKLAND. FreePhone 0508 375 394. Marketed by Radiant Health Limited. Phone: 09 972 1398. TAPS Approval No: PP2738.

Topical Cream
EFUDIX[®]
fluorouracil