

Topical Cream

EFUDIX[®]

fluorouracil



Treatment with Efudix[®] Questions & Answers

This brochure is for patients who have been prescribed Efudix for the treatment of **actinic keratoses / solar keratoses (AK/SK)** or **Bowen's disease**.

Your doctor has prescribed you treatment with Efudix cream.

Your doctor has prescribed Efudix (fluorouracil) because you have been diagnosed with one or both of the following skin conditions:^{1,2}

- **Actinic keratoses / solar keratoses (AK/ SK)**
 - Also known as ‘sunspots’
- **Bowen’s disease**
 - Also known as ‘squamous cell carcinoma (SCC) in situ’ or ‘intraepidermal SCC’

This leaflet helps explain what to expect during your treatment with Efudix and how to use the medication most effectively.

Be sure to read through this leaflet as well as the Consumer Medicine Information (CMI) before commencing your treatment with Efudix. For a copy of the CMI, ask your pharmacist.

Your diagnosis

☐ You have been diagnosed with solar keratoses (SK)

Actinic or solar keratoses are more common in people with fair skin and result from repeated exposure of the skin over many years to the ultraviolet (UV) radiation in sunlight. AK/SKs usually appear as thickened, scaly patches of skin or pink/brown spots on the face and scalp. It is important to treat AK/SK lesions because, in a small number of cases, they can develop into skin cancer.²⁻⁵

☐ You have been diagnosed with Bowen's disease

Bowen's disease is a non-invasive cancer of the outer layer of skin. It appears as dull, red, sharply defined, round to oval, raised, crusted and scaling patches and plaques. These lesions result from many years of exposure to the UV radiation in sunlight. They most commonly occur on the head, neck, trunk, arms or lower legs.^{2,6}

About Efudix

What is Efudix?

Efudix is a prescription-only treatment you apply to your skin at home. The active ingredient in Efudix is fluorouracil, which is a type of anti-cancer medicine that is able to destroy precancerous and cancerous skin cells while having little effect on normal cells.²

How does Efudix work?

Efudix is believed to work by interfering with a cell's ability to reproduce. Precancerous and cancerous skin cells multiply quicker than normal cells, and as a result can absorb more Efudix than the surrounding normal cells. In this way, Efudix is able to destroy the abnormal skin cells while having less of an effect on the healthy skin cells.¹⁻⁵

What can I expect during treatment with Efudix?

During treatment, the areas of your skin being treated may become inflamed and feel irritated. This is expected and is not always a cause for concern. The redness, crusting and peeling you see are signs that the medication is working to eliminate the skin lesions.¹⁻⁴

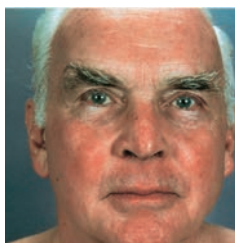
You may also find that areas of your skin where there were no lesions before may become red and inflamed. This is because abnormal skin cells may be present under the skin's surface, and Efudix also works to destroy these abnormal skin cells along with the visible lesions that you can see (refer to the images on the next page depicting the expected response).^{1,2,5}

While this stage of treatment may be uncomfortable and distressing, it is important that you **DO NOT STOP THERAPY** without checking with your doctor first. Your doctor or pharmacist can advise you about how to cope with the inflammation.²

EXPECTED RESPONSE OVER THE COURSE OF TREATMENT WITH EFUDIX

(Response may vary from patient to patient)

Before

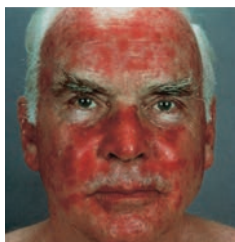


Typical response



Mild response

During

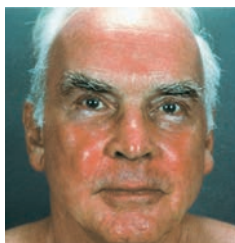


Typical response

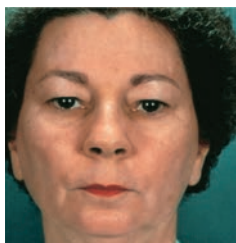


Mild response

After



Typical response



Mild response

These images are non-retouched images of real patients.

How to use Efudix

When do I apply Efudix?

For treatment of solar keratosis, Efudix is typically applied to the affected area once or twice a day, usually in the morning and evening, and ideally at the same times each day. Your doctor may give you different directions. It is important to carefully follow all directions given by your doctor.^{1,2} For treatment of Bowen's disease your doctor will give you specific instructions.

It's advised not to apply Efudix right before bedtime, as contact with pillowcases or sheets may result in undesirable spreading to normal skin that does not need treatment. Efudix should be applied at least 1.5-2 hours before going to bed to allow enough time to be completely absorbed into the skin.²

How do I apply Efudix?^{1,2}

1. Wash the skin to be treated using lukewarm water. Avoid soap or other cleansing products that may sting or irritate your skin, especially as treatment progresses.
2. Pat dry the affected area with a soft white paper towel. Allow 15 minutes for your skin to completely dry.
3. Apply a thin film of Efudix to the affected skin using a non-metal applicator, cotton bud or rubber glove, smoothing it gently onto your affected skin. Do not use too much cream.
4. Wash your hands carefully and thoroughly immediately after using Efudix.

Some important things to note:^{1,2}

- Do not apply Efudix to broken skin or open cuts. It may be absorbed into the bloodstream and cause side effects.
- Do not allow Efudix to come into contact with mucous membranes, such as eyes, eyelids, nostrils and lips.
- Do not cover the treated area with bandages or gauze unless your doctor tells you to. If your doctor asks you to apply a dressing after using Efudix, apply a fresh dressing to the treated area(s) daily.

Again, your doctor may provide you with different or specific instructions on how to apply Efudix. Make sure to carefully follow your doctor's directions.

How long will I need to use Efudix?

Treatment with Efudix for solar keratosis usually continues for 3 to 4 weeks, however your doctor may direct you otherwise. They will advise you on how often and long to use Efudix. For Bowen’s disease your doctor will advise you how long to use Efudix for. ^{1,2}

When should I expect my skin to start getting irritated?

Skin irritation is typical and a sign that the medication is working. When Efudix is applied to the skin, the following response usually happens:^{1,2}

Within 3-5 days	Redness of the affected area
Within 10-14 days	Blistering, peeling and cracking with occasional open sores and some discomfort
14 days onwards	The treated skin will then flake away. Some redness of the skin will continue for some time after Efudix is stopped. Scarring is not expected.

How long after Efudix therapy will my skin look irritated?

The healing process is usually complete 1 to 2 months after the end of treatment, but this can vary depending on the number of lesions treated and the duration of your treatment. The healthy skin surrounding the treated area may occasionally become reddened but will soon resume its normal colour once treatment is stopped.^{1,2}

What should I do if I forget to use Efudix?

If you forget to use Efudix, DO NOT try to make up for the missed application(s) by applying more at your next application. Simply resume using it, as prescribed by your doctor. If you are unsure, please consult your doctor or pharmacist.²

Caring for your skin during Efudix treatment

What kind of follow-up care is needed?

Your doctor may want to see you during the course of your treatment and/or after you have finished treatment, to assess how your skin is healing. This will be at the discretion of your doctor. It is important to attend these follow-up appointments.²

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. They can best assess whether your reaction to Efudix is normal.²

Should I avoid sun exposure while using Efudix?

It is important to avoid exposure to the sun or other UV light (such as tanning booths) during and immediately following treatment with Efudix. Sun exposure can increase the intensity of your skin's reaction to Efudix. Before going outdoors, protect your skin with a wide-brimmed hat and clothing that covers your limbs, and apply a broad-spectrum sunscreen. **Do not apply sunscreen directly on the treatment area.**^{1,2}

After your treatment with Efudix is completed, continue to use sunscreen every day to protect your skin from future exposure to UV light.

Can I wear cosmetics or use moisturisers while using Efudix?

Unless instructed by your doctor, you should avoid using cosmetics or any other skin products on the treatment area during Efudix therapy. This includes creams, lotions, sunscreen and other medications. This is because your treated skin is expected to become irritated and uncomfortable while using Efudix and applying other products directly on the treatment area may worsen your discomfort.^{1,2}

I noticed some other spots on my legs. Can I use Efudix here too?

Only your doctor can determine if the 'spots' you have are solar keratoses and/or Bowen's disease. This is why it is important to use Efudix only as directed and discuss any questions you may have with your doctor.²

Can I wash my hair while using Efudix?

Yes. It is recommended to shower and shampoo your hair first, then apply Efudix after drying your skin and hair properly.

Can I get a haircut while using Efudix?

Yes, but avoid applying Efudix immediately prior to your appointment.

Can I shave while using Efudix?

You may continue to shave while using Efudix but take care not to cut your skin in the treatment area. Since facial skin becomes inflamed during Efudix treatment, shaving with a conventional razor may become unpleasant. Instead, you may prefer to lightly shave with an electric razor or to clip your facial hair.²

Other important things to know about Efudix therapy:^{1,2}

- Do not share your Efudix with others, even if they seem to have the same condition as you.
- Avoid putting Efudix in contact with any mucous membranes (e.g. mouth, eyes, nostrils, vagina, anus) because of the risk for irritation.
- The most frequent side effects of Efudix include itching, burning, soreness, tenderness, crusting and redness. Other side effects not listed here may also occur in some people. **Tell your doctor immediately if you experience severe pain or ulceration at the treatment area.**
- Efudix has a shelf life of 5 years and the expiry date can be found on the packaging.^{1,7} Heat and dampness can destroy some medicines, so keep Efudix in a cool dry place (below 30°C) where children can't reach it.²

One last thing before you start treatment!

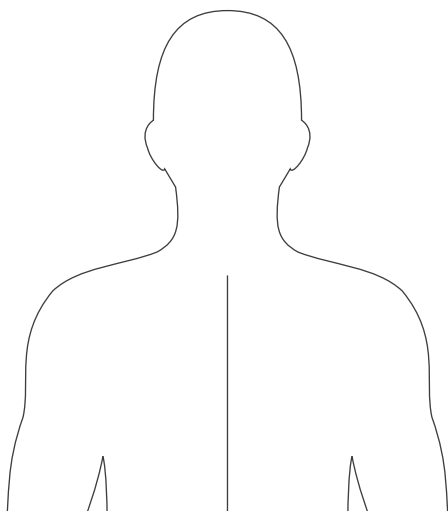
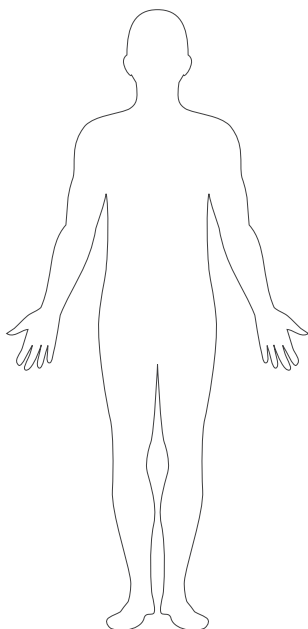
Before you start using Efudix, read the Consumer Medicine Information which you can ask your pharmacist to provide. Use only as directed by your healthcare professional.

Remember, AK/SK and Bowen's disease are the result of prolonged and cumulative exposure to harmful UV radiation. Ask your doctor about ways to protect your skin from sun-damage related skin conditions in the future and treating underlying sun-damage to your skin.

This leaflet does not contain all the available information on Efudix, and it does not take the place of talking to your doctor or pharmacist.

Your treatment instructions

Treat the areas indicated by your doctor and follow their directions carefully.



Date _____ Time _____

[illegible]

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fluorouracil

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.^{1,2}

References: 1. Efudix Product Information. 2. Efudix Consumer Medicine Information. 3. Lanoue J, et al. *Cutis* 2015;96(3):165-72,93. 4. Chia A, et al. *Aust Fam Physician* 2007;36(7):539-541. 5. Askew DA, et al. *Int J Dermatol* 2009;48(5):453-463. 6. Neagu TP, et al. *Rom J Morphol Embryol* 2017;58(1)33-40. 7. Australian Register of Therapeutic Goods (ARTG) Public Summary for ARTG Entry 13721 (Efudix fluorouracil 5%w/w cream tube); July 2020.