

Efudix®

Fluorouracil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Efudix. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Efudix against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Efudix is used for

What it does

Efudix is used to treat the following skin conditions:

- Solar keratoses, also known as actinic keratoses or sun spots.
- Bowen's disease (type of skin cancer).

Solar keratoses are rough, red, scaly, or crusty spots on the skin that are caused by too much exposure to sunlight. They are more common on sun-exposed areas, such as the face, nose, ears, chest, forearms, and back of the hands.

Solar keratoses are usually harmless, but there is a small risk that they may eventually turn into skin cancer.

Bowen's disease causes one or more small patches of scaly red skin. It occurs when there is a growth of

abnormal cells in the outer layer of skin. It is most commonly found on the lower leg.

Ask your doctor if you have any questions about why Efudix has been prescribed for you.

Your doctor may have prescribed Efudix for another reason.

How it works

Efudix contains the active ingredient fluorouracil.

Fluorouracil belongs to a group of medicines called anti-cancer medicines that are applied to the skin.

It works by destroying precancerous and cancerous cells, while having little effect on normal cells.

Efudix is available only with a doctor's prescription.

Before you use Efudix

When you must not use it

Do not use Efudix if you have an allergy to:

- Any medicine containing fluorouracil
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

Do not use this medicine if you have a dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.

Do not use this medicine if you are pregnant or planning to become pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breastfeed if you are using this medicine.

It is not known if the active ingredient in Efudix passes into breast milk and if there is a possibility that your baby may be affected.

Do not use Efudix after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Efudix, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Efudix contains the parabens methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions. It is also contains stearyl alcohol and propylene glycol, which may cause skin irritation.

Tell your doctor if you have any other health problems including:

- Inflammatory skin conditions such as darkening of skin during pregnancy (chloasma) or a chronic rash (rosacea).

Tell your doctor if you work outside for long periods of time during the day.

Efudix is not recommended for people who work outdoors for long periods of time.

If you have not told your doctor about any of the above, tell them before you use Efudix.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you bought from a pharmacy, supermarket or health food shop.

Some medicines and Efudix may interfere with each other.

How to use Efudix

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How to use it

Follow these steps:

- Wash the skin to be treated using lukewarm water. Avoid soap or other cleansing products which may sting or irritate your skin, especially as treatment progresses.
- Pat dry the affected area with a soft white paper towel.
- Allow 15 minutes for your skin to completely dry.
- Apply Efudix to the affected skin as advised by your doctor.
- Use a non-metal applicator, cotton bud or a rubber glove to apply a thin film of Efudix, smoothing it gently onto your affected skin. Do not use too much cream.
- Be very careful not to allow Efudix to come into contact with mucous membranes, such as eyes, eyelids, nostrils and lips.

- Do not apply to broken skin or open cuts as it may be absorbed into the bloodstream and may cause side effects.
- Wash your hands carefully and thoroughly immediately after using Efudix.
- Do not cover the treated area unless your doctor tells you to.
- If your doctor asks you to apply a dressing after using Efudix, apply a fresh dressing to the area(s) daily.
- The total area of skin treated with Efudix at any time should not exceed 500 sq cm (approx. 23 x 23cm). Treat larger areas a section at a time.

When to use Efudix

Apply Efudix once or twice daily as advised by your doctor.

Apply in the morning and then again in the late afternoon or early evening.

Do not apply Efudix immediately before going to bed.

Apply Efudix at least 1.5 - 2 hours before bedtime to enable complete absorption and prevent wiping off onto pillowcases and sheets. Contact with pillowcases or sheets may result in undesirable spreading of Efudix to normal skin that does not need treatment.

Use your medicine at about the same time each day.

Using Efudix at the same time each day will have the best effect. It will also help you remember when to use it.

How long to apply Efudix

Continue using Efudix for as long as your doctor has told you to.

Continue treatment up until the ulceration stage, usually 3 to 4 weeks. The healing process is usually complete 1 to 2 months after the end of treatment. The healthy skin surrounding the treated area may occasionally become reddened, but will soon resume its normal colour once treatment is stopped.

If you forget to use it

Do not try to make up for the application you missed by applying more at the next application.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose) or swallow the cream

Immediately telephone your doctor or the Poisons Information Centre (tel: 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you get Efudix in your eyes, nose or mouth or you think that you or anyone else may have used too much Efudix. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Efudix

Expect your appearance to look worse and to feel uncomfortable while treatment is in progress.

Sometimes it can take several weeks after treatment with Efudix has stopped before you see any improvement in your condition.

When Efudix is applied to the skin, the following usually happens:

- A redness of the affected area (generally within 3 to 5 days)
- Followed by blistering, peeling, and cracking (within 11 to 14 days) with occasional open sores and some discomfort
- 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.

Things you must do

Limit your exposure to sun during and immediately following treatment with Efudix.

This will help reduce the likelihood and severity of unwanted side effects.

Apply a broad spectrum sunscreen (SPF 30 or higher) every day before going outdoors, and regularly reapply during the day, except directly on the treatment area.

Efudix can make you more sensitive to sunlight. In addition to sunscreen, wear a wide-brimmed hat, long sleeves and trousers (or a long skirt) to protect your skin.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Efudix.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using Efudix stop using it and tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Always discuss with your doctor any problems or difficulties experienced during or after using Efudix.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use Efudix to treat other complaints unless your doctor tells you to.

Do not stop using Efudix or change the dose without checking with your doctor.

Do not let Efudix come into contact with the eyes, eyelids, nostrils or mouth.

Efudix is highly irritating to sensitive skin and the eyes.

Things to be careful of

While treatment is in progress follow these personal care tips:

Avoid using cosmetics or other topical medications, including sunscreens, directly on the treatment area, unless directed by your doctor.

Your treated skin is expected to become irritated and uncomfortable whilst using Efudix. Applying other products directly on the treatment area may make your discomfort worse.

You may continue to shave whilst using Efudix, but take care not to cut your skin in the treatment area.

As facial skin becomes inflamed during Efudix treatment shaving with a conventional razor may become unpleasant. You may prefer instead to lightly shave with an electric razor or clip the facial hair.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Efudix.

Efudix helps most people with skin conditions caused by ageing or exposure to sunlight, but it can have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

During treatment with Efudix expect to have a temporary unsightly appearance and discomfort at the sites where you apply the cream.

The most common side effects of Efudix are a sign that the medicine is working and include:

- soreness and pain
- itchiness and irritation
- darkening or reddening of the skin
- burning

- crusting
- increased sensitivity of the skin to the sun
- rash
- dermatitis
- scarring.

These side effects are usually short-lived.

Tell your doctor or pharmacist if any of the above side effects become too uncomfortable for you.

Tell your doctor immediately if you experience severe pain or ulceration at the site of application.

Discontinue Efudix immediately and contact your doctor if you experience any of the following side effects:

- Stomach problems such as severe pain, cramps, bloody diarrhoea and vomiting
- Swelling and soreness of the mouth and tongue
- Fever and chills.

These are serious side effects. You may need urgent medical attention.

Serious side effects are rare.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Efudix

Storage

Keep Efudix in a cool dry place where the temperature stays below 30°C.

Protect from heat.

Do not store Efudix or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

AUST R 13721

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Efudix looks like

Efudix is a white cream that comes in a 20g aluminium tube.

Ingredients

Efudix contains 5% w/w fluorouracil as the active ingredient. It also contains:

- methyl hydroxybenzoate
- soft white paraffin
- polysorbate 60
- propyl hydroxybenzoate
- propylene glycol
- stearyl alcohol
- water - purified

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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