

New Zealand Consumer Medicine Information

EFUDIX

Fluorouracil 5% w/w Cream

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 using 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

Efudix is used to treat:

- Superficial pre-malignant and malignant skin lesions
- Keratoses including senile, actinic and arsenical forms
- Bowens disease (type of skin cancer); and
- Superficial Basal-Cell Carcinoma.

It contains the active ingredient fluorouracil.

Efudix belongs to a group of medicines called topical anti-cancer (also called antineoplastic or cytotoxic) medicines.

Topical anti-cancer medicines are used on the skin to treat conditions caused by ageing or exposure to sunlight (solar keratoses). If left untreated, these conditions may develop into skin cancer.

Efudix is also used to treat Bowen's disease and superficial Basal Cell Carcinomas, which are types of skin cancer.

You should be aware that you may look worse while treatment is in progress 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.

Although the skin seems to be worse, it is a sign that the medication is working. The treated skin will flake away. Some redness of the skin will continue for some time after the medicine is stopped. Scarring would not be expected.

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

Your doctor, however, may have prescribed Efudix for another purpose.

This medicine 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 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 breast-feed if you are using this medicine.

It is not known if the active ingredient in Efudix passes into breast milk and 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 if you should be using Efudix, talk to your doctor.

Before you start to use it

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

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

- inflammatory skin conditions including darkening of skin during pregnancy (chloasma) or a chronic rash (rosacea)

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 have 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 to using Efudix:

- Apply Efudix as advised by your doctor.
- Apply a thin layer of Efudix to the affected areas of your skin. Use with caution if used around eyelids nose and lips.
- Apply Efudix preferably with a nonmetal applicator or a rubber glove. If you use your fingers to apply Efudix or your hands come into contact with Efudix wash them thoroughly. Do this immediately after use.
- Although not generally required, your doctor may recommend that you apply a fresh occlusive dressing to the area(s) daily. If an occlusive dressing is used there may be a higher chance of experiencing an inflammatory reaction on the adjacent normal skin
- Always follow your doctors' directions and apply Efudix for the length of time that has been prescribed to achieve the best results. If you have any questions call your doctor and be sure to keep your scheduled appointments.

The total area of skin being treated with Efudix at any time should not exceed 500cm² (approx. 23 x 23 cm) Larger areas should be treated a section at a time.

When to use Efudix

Apply Efudix thinly to the affected area once or twice daily as advised by your doctor. It should be applied in the morning and late afternoon or early evening. Do not apply Efudix immediately before going to bed.

Use your medicine at about the same time each day.

Using it 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.

Treatment should continue up until the ulceration stage, usually three to four weeks. The healing process is usually complete one to two months after the end of treatment. The healthy skin surrounding the area being treated may occasionally become reddened, but soon resumes 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 or ingest the cream (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia 13 11 26; New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much or ingested Efudix. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Efudix

Things you must do

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 advised to by your doctor.

Do not stop using your medicine without checking with your doctor.

Do not let Efudix come into contact with mucous membranes or the eyes.

Efudix is highly irritating to sensitive skin and the eyes.

Things to be careful of

While treatment is in progress, avoid:

- cosmetics or other topical medication applied to the treatment area, unless directed by your doctor.
- exposing treated areas to sun for prolonged periods. This may increase irritation in the areas being treated.
- treatment around the eyes and nose unless directed by your doctor.

Be aware that you may look worse while treatment is in progress.

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 may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- pain
- itchiness
- darkening of the skin
- burning at the site of application

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- dermatitis
- scarring
- soreness
- tenderness

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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.

During treatment with Efudix temporary unsightly appearance and local discomfort is to be expected.

After using Efudix

Storage

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

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.

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 Efudix 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 which comes in a metal tube.

Ingredients

Efudix contains 5% Fluorouracil as the active ingredient. It also contains:

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

Efudix comes in a 20 g tube.

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

Sponsor:

Valeant Pharmaceuticals New Zealand Ltd
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Mangere
AUCKLAND

Telephone: 09-257-0521

Trademark: EFUDIX is a trademark

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29 June 2010

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