

# New Zealand Consumer Medicine Information

## EFUDIX

### *Fluorouracil 5% w/w Cream*

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## What is in this leaflet

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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.

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## What Efudix is used for

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### ***What it does***

Efudix is used to treat precancerous and cancerous growths, affecting the outer layer of skin, caused by ageing or exposure to sunlight including:

- Keratoses, including senile, actinic and arsenical forms (also known as sun spots)
- Bowen's disease (type of skin cancer)
- Superficial Basal Cell Carcinoma (type of skin cancer); and
- Keratoacanthoma.

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.

Keratoacanthoma is a growth that breaks out in sun damaged skin or hair bearing skin. They usually grow rapidly and then may shrink and go away without treatment.

**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.

### ***How it works***

Efudix contains the active ingredient fluorouracil and belongs to a group of medicines called anti-cancer medicines (also called antineoplastic or cytotoxic medicines) that are applied to the skin. It works by destroying precancerous and cancerous cells, while having little effect on normal cells.

This medicine is available only with a doctor's prescription.

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## **Before you use Efudix**

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### ***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 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 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.**

Efudix contains the parabens methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions. It 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 including 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 have bought from a pharmacy, supermarket or health food shop.**

Some medicines and Efudix may interfere with each other.

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## **How to use Efudix**

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**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***

**To use Efudix follow these steps:**

- Apply Efudix as advised by your doctor.
- Using a non-metal applicator, cotton bud or a rubber glove, apply a **thin** layer of Efudix to the affected areas of your 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.
- Wash your hands carefully and thoroughly immediately after using Efudix.
- If your doctor asks you to apply an occlusive dressing after using Efudix, apply a fresh occlusive 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 23 cm). 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.**

Contact with pillows 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 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 (overdose) or swallow the cream***

**Immediately telephone your doctor or the New Zealand National Poisons Centre 0800 POISON (0800 764 766) for advice, or go to the Emergency Department at your nearest hospital, if you get Efudix in your eyes, nose or mouth or if 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.

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## **While you are using Efudix**

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

Although the skin seems to be worse, it is a sign that the medication is working. 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).
- Then blistering, peeling, and cracking (within 11 to 14 days) with occasional open sores and some discomfort.
- The treated skin will flake away.

- Some redness of the skin will continue for some time after the medicine 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.

**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 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, avoid:**

- Cosmetics or other topical medication applied to the treatment area, unless directed by your doctor.
- Exposing treated areas to the sun or other forms of UV radiation for prolonged periods. This may increase irritation in the areas being treated.
- Treatment around the eyes, mouth and nose unless directed by your doctor.

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## Side effects

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**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:

- pain
- itchiness
- darkening or reddening of the skin
- burning or ulceration at the site of application
- crusting
- irritation
- inflammation
- increased sensitivity of the skin to the sun
- rash
- dermatitis
- scarring
- soreness.

These side effects are usually mild and short-lived.

**Tell your doctor or pharmacist if you notice any of the above side effects and they worry you.**

**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.

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## **After using Efudix**

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### ***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.

**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.**

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## **Product description**

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### ***What Efudix looks like***

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

### ***Ingredients***

Efudix contains 5% 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***

iNova Pharmaceuticals (New Zealand) Limited  
c/- Simpson Grierson  
88 Shortland Street,  
Auckland 1141  
Toll-free number: 0508 375 394

Trademark: EFUDIX is a trademark

***Date of information***

29 January 2018