

Package leaflet: Information for the user
Efudix 5% w/w Cream
Fluorouracil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Efudix Cream is and what it is used for
2. What you need to know before you use Efudix Cream
3. How to use Efudix Cream
4. Possible side effects
5. How to store Efudix Cream
6. Contents of the pack and other information

1. WHAT EFUDIX CREAM IS AND WHAT IT IS USED FOR

Efudix Cream belongs to a group of anti-cancer medicines.

Efudix Cream is used to treat certain skin conditions caused by abnormal cell growth including different types of keratosis (a horny growth of the skin), keratocanthoma (a firm nodule on the skin), Bowen's disease, and some simple skin cancers.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EFUDIX CREAM

Do not use Efudix Cream:

- If you are pregnant, think you may be pregnant, or are breast feeding.
- If you are allergic to fluorouracil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking antiviral nucleoside drugs (e.g. brivudine)

Warnings and precautions

Talk to your doctor or pharmacist before taking Efudix Cream.

- The cream should be kept away from your eyes and mucosal surfaces (such as mouth, nose, genital or anus). (see section 3, 'How to use Efudix Cream')
- If you have broken, inflamed or ulcerated skin as this can lead to too much cream being absorbed into the blood, which very rarely can cause side effects.
- if you know that you have reduced or no activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (partial or complete DPD deficiency).
- Exposure to UV-radiation (e.g. natural sunlight, tanning salon) should be avoided.
- Closing bandages or dressing may increase inflammatory reactions to the skin
- It is unlikely that the treatment will have any effect on your ability to drive or use machines

Children

Efudix Cream is not recommended for use in children.

Other medicines and Efudix Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breastfeeding

Do not use Efudix Cream, and tell your doctor if you are pregnant, think you might be pregnant or you are breastfeeding.

Women of childbearing potential should use effective contraceptive measures while being treated with fluorouracil and for six months following completion of treatment.

Men should use effective contraceptive measures and not father a child while being treated with fluorouracil and for three months following completion of treatment.

Driving and using machines

It is unlikely that treatment will have any effect on the ability to drive and use machines when used according to the dosage instructions.

Efudix Cream contains Stearyl alcohol, propylene glycol and parahydroxybenzoates

Efudix Cream contains some ingredients that may cause side effects. These are:

- Stearyl alcohol and propylene glycol, which may cause local skin irritations (e.g. contact dermatitis, which is an inflammation of the skin).
- Methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

3. HOW TO USE EFUDIX CREAM

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you think that the effect of your medicine is too weak or strong, talk to your doctor. Do not change your dose without asking your doctor.

Efudix cream is for topical application. Do not use Efudix Cream in or near your eyes, mouth, nose or around your genitals or anus. If any cream does get in or into these parts of your body, wash them immediately with water.

Apply a thin layer of the cream to the affected area as instructed by your doctor. The cream is usually used once or twice a day for at least three to four weeks.

Wash your hands thoroughly after using this cream.

Your doctor will tell you if you need to apply a dressing to the treated skin.

Never treat an area of skin larger than 23 x 23cm (9x9 inches) at any one time. This area is approximately the size of a dinner plate.

Your skin may appear to be worse after you start the treatment. This is to be expected because of the way that Efudix Cream works and you should continue to apply the cream, as directed.

Efudix Cream works by destroying abnormal cells. This causes redness, discomfort, blistering and darkening of the affected areas before new skin cells grow. If your skin becomes much worse, or if you are worried, consult your doctor. After stopping treatment you may find that your skin takes one to two months to heal completely.

Use in Children

Efudix Cream is not recommended for use in children.

If you use more Efudix Cream than you should

If you accidentally apply too much cream or some cream is accidentally swallowed, contact your doctor, pharmacist or go to your nearest hospital straight away.

If you forget to use Efudix Cream

If you miss a dose, apply the cream as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not apply a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The usual response to treatment with Efudix is described in section 3, under 'How to use Efudix Cream'.

The cream may sometimes cause redness and discomfort in the surrounding healthy skin and skin allergy may develop. Occasionally sores will develop and you may feel some discomfort. Rarely, they are round, red and painful. If you are suffering severe discomfort, your doctor may be able to help.

Whilst using Efudix your skin may become more sensitive to sunlight.

The following side-effects have been reported:

Very rare: blood disorders, allergic conditions (e.g. hypersensitivity), diarrhoea, vomiting, abdominal pain, inflamed and sore mouth, skin reaction and pain, skin irritation, skin swelling, skin ulcer, photosensitivity, hair loss, fever, chills, irritation of the mucus membranes

Frequency not known: unpleasant taste, headache, dizziness, eye irritation or inflammation, increased secretion of tears, nausea, bleeding at the application site

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland

HPRA Pharmacovigilance, Website: www.hpra.ie.

Malta

ADR Reporting website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EFUDIX CREAM

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C.

Once opened, use the cream within 90 days for 20g and 40g tubes.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Efudix Cream contains

The active substance is Fluorouracil. Efudix cream contains 5% w/w fluorouracil.

The other ingredients are Stearyl alcohol, white soft paraffin, polysorbate 60, propylene glycol (E1520), methyl parahydroxybenzoate (methyl paraben) (E218), propyl parahydroxybenzoate (propyl paraben) (E216) and purified water.

What Efudix Cream looks like and contents of the pack

Efudix Cream is a smooth, white, opaque cream. It comes in tubes of 20g and 40g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Viatis Healthcare Limited,
Damastown Industrial Park,
Mulhuddart,
Dublin 15
DUBLIN,
Ireland

Manufacturer

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35-105 Rzeszów, Poland

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