Package leaflet: Information for the user

Efudix 5% Cream

Fluorouracil

Read all of this leaflet carefully before you start using 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

Efudix Cream is used to treat skin conditions such as growths of the skin (keratoses) and some simple skin cancers. The active ingredient fluorouracil belongs to a group of anti-cancer medicines.

Important Information about How Efudix Works
Efudix destroys cancerous and pre-cancerous cells, while having little effect on normal cells.

When you use Efudix it is likely that the area of the skin that you are treating will become red. This will probably be followed by inflammation/ swelling, possibly some discomfort, skin erosion and eventually, healing. This is the expected normal response to treatment and shows that Efudix is working.

Sometimes the response is more severe (see section 4 “Possible Side Effects”). If your skin becomes much worse, you experience pain or if you are worried, talk to your doctor. Your doctor may prescribe you another cream to relieve any discomfort.

After stopping treatment, you may find that your skin takes one to two months to heal completely.

Efudix will also treat abnormalities of the skin that were previously not visible to the naked eye, and these abnormalities may become red and inflamed.

2. What you need to know before you use Efudix Cream

Do not use Efudix Cream:
- if you are allergic to fluorouracil or any other ingredients in this medicine (listed in section 6).
- if you are pregnant, think you may be pregnant, or are breast-feeding.
- if you are using any medicines known as antiviral nucleosides (e.g. brivudine, sorivudine).

These medicines are usually used to treat chickenpox or shingles.

Warnings and precautions

Talk to your doctor or pharmacist before taking Efudix Cream:
- if you know that you have reduced or no activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (partial or complete DPD deficiency).

Take special care with Efudix Cream if you:
- are applying this cream around your eyelids, nose or lips, and avoid contact with the eyes or mouth (see section 3, "How to use Efudix Cream").
- have open cuts. Do not use this cream on open cuts as this can lead to too much cream being absorbed into the blood, which very rarely, can cause side effects.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Sunlight may increase the effects of Efudix. This may result in increased skin reactions. To prevent this you must try to stay out of direct sunlight as much as possible while using the cream and must not use a sunlamp or sun bed.

Exposure to UV-radiation (e.g.) natural sunlight, tanning salon) should be avoided. Closing bandages or dressing may increase inflammatory reactions of the skin.

Children and adolescents

Efudix Cream is not for use in anyone under 18 years of age.

Other medicines and Efudix Cream
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is **very important**, as

using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

In particular, tell your doctor if you are using:

- **medicines to treat chickenpox or shingles (brivudine, sorivudine)** or have used them in the last 4 weeks. These medicines may increase the possibility of unwanted effects with Efudix Cream.

Pregnancy, breast-feeding and fertility
Do not use Efudix Cream and tell your doctor if you are pregnant, think you might be pregnant.

Females of childbearing potential under treatment must use effective contraceptive during treatment and for 7 months after treatment.

Male patients (or their female partners of childbearing potential) must use effective contraception during treatment and for four months after treatment.

If you become pregnant during treatment inform your doctor immediately and make use of genetic counselling.

Do not use Efudix Cream and tell your doctor if you are breast-feeding. If use during breastfeeding is absolutely necessary, breast-feeding must be discontinued.

The use of Efudix Cream may impair female and male fertility. Efudix Cream is not recommended in men attempting to father a child.

Driving and using machines
It is unlikely that the treatment will have any effect on your ability to drive or use machines.

Efudix Cream contains

- **Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216):** May cause allergic reactions (possibly delayed).
- **Propylene glycol:** May cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist.
- **Stearyl alcohol:** May cause local skin irritations (e.g. contact dermatitis, which is an inflammation of the skin).

Do not use Efudix if you are allergic to any of its ingredients.

3. How to use Efudix Cream

Always use this medicine exactly as your doctor 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.

If you swallow some cream contact your doctor, pharmacist or go to your nearest hospital **straight away.**

If any of the following occur, wash the cream off using water, then contact your doctor, pharmacist or go to your nearest hospital **straight away:**
- You get this cream in your eyes, nose or mouth.
- Someone else accidentally uses this cream.

How to apply Efudix
- Only use Efudix Cream on the skin and avoid contact with the eyes and mouth.
- Apply a thin layer of the cream to the affected area as instructed by your doctor.
- It is **very important** that you do not use too much cream and do not apply the cream on open cuts. This may lead to some cream being absorbed into the blood and, very rarely, this can cause side effects.

- 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 23 cm (9 x 9 inches) at any one time. This area is approximately the size of a dinner plate.

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.

4. Possible side effects

Like all medicines, Efudix Cream can cause side effects, although not everybody gets them. The usual response to treatment with Efudix is described in Section 1, under "How Efudix works".

You must tell your doctor IMMEDIATELY if you experience any of these side effects:
- Stomach problems such as pain, cramps, diarrhoea and vomiting
- Swelling and soreness of the mouth and tongue
- Fever or feeling generally unwell.

These side effects may occur if you use too much cream or if you apply the cream to open cuts.

Other side effects are:
Very rare (may affect up to 1 in 10,000 people)
- Relating to the skin and subcutaneous tissue: itching, redness, burning sensation, severe peeling, intense swelling or inflammation, ulceration, blistering, irritation, pain, hives and rash. These are generally a severe response to treatment and usually occur in the areas of the skin where the cream has been applied. Exposure to sunlight may increase the intensity of the reaction.
- Rash on areas other than where the cream was applied
- Hair loss

Not known (frequency cannot be estimated from the available data)
- Painful and/or watering eyes
- Taste disturbance
- Headache, dizziness, nausea
- Bleeding at the application site.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

For 20 g and 40 g tubes: Once opened, use within 90 days.

Do not use Efudix Cream after the expiry date which is stated on the tube and the outer carton after "EXP". The expiry date refers to the last day of that month.

Do not store Efudix Cream above 30°C.

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 to protect the environment.

6. Contents of the pack and other information

What Efudix Cream contains

Active substance:	Fluorouracil (at a 5% concentration).
Other ingredients:	Stearyl alcohol, white soft paraffin, polysorbate 60, propylene glycol, E218 (methyl parahydroxy-benzoate), E216 (propyl parahydroxybenzoate), purified water.

What Efudix Cream looks like and contents of the pack
- Efudix is a white, opaque cream.
- It is supplied in tubes of 20 g and 40 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer responsible for batch release
ICN Polfa Rzeszów S.A., ul. Przemysłowa 2, 35-959 Rzeszów, Poland

For any information about this medicine, please contact the Marketing Authorisation Holder.

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