Efudix® 5% w/w Cream
(fluorouracil)

1. WHAT EFUDIX IS AND WHAT IT IS USED FOR

Efudix 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. BEFORE YOU USE EFUDIX

Do not use Efudix if you:

• are allergic (hypersensitive) to fluorouracil or any other ingredients in this medicine (these are listed in section 6, “Further Information”).
• are pregnant, think you may be pregnant, or are breast-feeding.
• are using any medicines known as antiviral nucleosides (e.g. brivudine, sorivudine). These medicines are usually used to treat chickenpox or shingles.

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

Take special care with Efudix 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”).
• 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.
• have reduced activity/deficiency of the enzyme DPD (dihydropyrimidine dehydrogenase).

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.

Using other medicines

Tell your doctor or pharmacist if you are taking or have recently taken 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.

Pregnancy and breast-feeding

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

Driving and using machines

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

Important information about some of the ingredients of Efudix

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

• stearyl alcohol and propylene glycol, which can cause local skin irritations (e.g. contact dermatitis, which is an inflammation of the skin).
EFUDIX

How to apply Efudix

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

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 the missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Efudix 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".

The unwanted effects are:

- 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.

- Painful and/or watering eyes.
- Hair loss.
- Taste disturbance.

General side effects:

- Sores which are red, round and painful.
- Rash on areas other than where the cream was applied.
- Other side effects may occur if you use too much cream or if you apply the cream to open cuts. These side effects are listed below.

The following side effects with a frequency not known have been recorded: headache, dizziness, nausea

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

5. HOW TO STORE EFUDIX

Store Efudix out of the sight and reach of children.

Do not store above 30°C.

Do not refrigerate or freeze.

Once opened use within 90 days.

Do not use Efudix 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.

Any unused Efudix should be returned to your pharmacist for safe disposal.

If your medicine gets discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

Each tube contains 40g of 5% fluorouracil.

Also contains stearyl alcohol, white soft paraffin, polysorbate 60 (E435), propylene glycol (E1520), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water.

What Efudix looks like and contents of the pack

- Efudix cream is white and opaque.
- It is available in tubes of 40 grams.

Manufacturer

Manufactured by ICN Polfa Rzeszów S.A., ul. Przemysłowa 2, 35-959 Rzeszów, Poland

Procured from within the EU & repackaged by Product Licence holder: Kosei Pharma UK Limited, 956 Buckingham Avenue, Slough Trading Estate, Slough, SL1 4NL, UK

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These abnormalities may become red and inflamed. That were previously not visible to the naked eye, and Fluorouracil takes one to two months to heal completely. After stopping treatment you may find that your skin discomfort. If you experience any side effect and this becomes serious, tell your doctor or pharmacist.

Fluorouracil is not for use in anyone under 18 years of age. Take special care with Fluorouracil 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 Fluorouracil"). 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. have reduced activity/deficiency of the enzyme DPD (dihydropyrimidine dehydrogenase). Sunlight may increase the effects of Fluorouracil. 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.

Using other medicines
Tell your doctor or pharmacist if you are taking or have recently taken 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 Fluorouracil.

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

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

Important information about some of the ingredients of Fluorouracil
Fluorouracil contains some ingredients that can cause side effects. These are: stearyl alcohol and propylene glycol, which can cause local skin irritations (e.g. contact dermatitis, which is an inflammation of the skin).
• E218 (methyl parahydroxybenzoate) and E216 (propyl parahydroxybenzoate), which can cause allergic reactions. Do not use Fluorouracil if you are allergic to any of its ingredients.

3. HOW TO USE FLUOROURACIL

Always use Fluorouracil exactly as your doctor has told you. You must 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 Fluorouracil

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

If you forget to use Fluorouracil

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 the missed dose.

4. POSSIBLE SIDE EFFECTS

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You must tell your doctor IMMEDIATELY if you experience any of these side effects:

- Stomach problems such as pain, cramps, diarrhoea and vomiting
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- Fever or feeling generally unwell.

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

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

5. HOW TO STORE FLUOROURACIL

- Store Fluorouracil out of the reach and sight of children.
- Do not store above 30°C.
- Do not refrigerate or freeze.
- Once opened use within 90 days.
- After use close the tube.
- Do not use Fluorouracil 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.
- Any unused Fluorouracil should be returned to your pharmacist for safe disposal.
- If your medicine gets discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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