1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Efudix (ointment)

Fluorouracil, 50 mg/g

Read all of this leaflet carefully before you start using Efudix

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Efudix has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What Efudix is and what it is used for

The active ingredient fluorouracil belongs to a group of anti-cancer medicines.Efudix destroys cancerous and pre-cancerous cells, while having little effect on normal cells.

Efudix is used to treat skin conditions such as growths of the skin (keratoses) and some simple skin cancers.

2. What you need to know before you use Efudix

Do not use Efudix:

- if you are hypersensitive (allergic) to fluorouracil or any of the other ingredients of Efudix;
- 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

Take special care with Efudix:

- if you know that you have reduced or no activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (partial or complete DPD deficiency);
- 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*);
- if you 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

Do not give Efudix to children as it is unlikely to be safe.

Other medicines and Efudix:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

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

Pregnancy and breastfeeding and fertility:

You should not use Efudix if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Efudix.

An effective method of contraception must be used during treatment with Efudix.

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

Driving and using machinery:

It is unlikely that Efudix may interfere with the daily activities of a patient.

Efudix contains methyl parahydroxybenzoate propyl parahydroxybenzoate propylene glycol stearyl alcohol:

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).

3. How to use Efudix:

- Do not share medicines prescribed for you with any other person.

- Always use Efudix exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.
- Your doctor will tell you how long your treatment with Efudix will last.
- If you have the impression that the effect of Efudix is too strong or too weak, tell your doctor or pharmacist.

If you use more Efudix than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of Efudix:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Efudix can have side effects.

Not all side effects reported for Efudix are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Efudix, please consult your healthcare professional for advice.

If any of the following happens, stop using Efudix and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Efudix. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- 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.

The following side effects have been reported but the frequency is unknown:

- Painful and/or watering eyes.
- Taste disturbance.
- Headache, dizziness, nausea.
- Bleeding at the application site.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Efudix.

5. How to store Efudix

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Do not refrigerate / freeze.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle .
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use Efudix 90 days after opening.

6. Contents of the pack and other information

What Efudix contains

- The active substance is:

  Fluorouracil
- The other ingredients are*:*

Stearyl alcohol, white soft paraffin, polysorbate 60, propylene glycol, E218 (methyl

parahydroxybenzoate), E216 (propyl parahydroxybenzoate), purified water.

What Efudix looks like and contents of the pack

What Efudix looks like:

White to almost white, homogenous, smooth, opaque ointment.

Contents of pack:

Efudix is packed in 20 g aluminium membrane-sealed tube coated inside with Valspar J3092 lacquer. The tube is closed with a polypropylene (PP) membrane-piercing caps.

Holder of Certificate of Registration and Manufacturer

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando,

Gauteng,

1601

This leaflet was last revised in

Date of registration: 03 November 1994

Date of revision of text: 1 September 2021

Registration number

D/13.8/122

NAMIBIA NS2
04/13.8/105

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website