PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a physician's prescription only

EFUDIX CREAM 5%

Composition:
Active ingredient:
Each gram of cream contains 50 mg of fluorouracil

For a list of inactive and allergenic ingredients in the medicine, see section 2 - "Before using the medicine" and section 6- "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your physician or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Efudix Cream 5% is used for the treatment of skin problems, such as keratosis and basal cell carcinoma (BCC). The active ingredient Fluorouracil.

Therapeutic group: Belongs to a group of anti-cancer medicines.

2. Before using the medicine

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient **fluorouracil** or to any of the additional ingredients that the medicine contains (please see section 6, "Additional information").
- You are pregnant, you think you may be pregnant or you are breastfeeding.
- You are using any medicines known as antiviral nucleosides (e.g., brivudine, sorivudine). These medicines are usually used to treat chickenpox or shingles.

Special warnings regarding the use of the medicine:
Before treatment with Efudix Cream 5%, tell your physician if:
- You suffer from inactivity or deficiency of the enzyme DPD (dihydropyrimidine dehydrogenase) (complete or partial deficiency of the enzyme).

Particular caution using Efudix Cream 5% is required in the following instances:
- When using the medicine, do not smoke or go near open flames – there is a risk of severe burns. Fabric (e.g., clothing, bedding, dressings, etc.) that comes in contact with this medicine burns more easily and is a serious fire hazard.
  Washing of clothing and bedding may reduce build-up of the medicine but do not remove it completely.
- Avoid contact of this medicine with your eyes or mouth, especially when the medicine is intended for the area of your eyelids, nose or lips (see section 3, "How should you use the medicine").
- Do not apply this medicine to open wounds. This may lead to increased absorption of the medicine into the blood which, very rarely, can cause side effects.
- Do not use this medicine on ulcerated or inflamed skin; this may lead to increased absorption of the medicine into the blood which, very rarely, can cause side effects.
- During use of **Efudix Cream 5%**, avoid direct exposure to sunlight, or sunlamps and sun beds, as much as possible, as these increase the effects of **Efudix Cream 5%** and may increase skin reactions.
- Exposure to UV radiation (e.g., natural sunlight, tanning salon) should be avoided.
- Closed bandages or band-aids may increase the inflammatory reaction of the skin.

Children and adolescents
This medicine is not intended for children and adolescents under 18 years of age.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform your physician or pharmacist. This is 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 physician if you are being treated with:
- Antiviral medicines for the treatment of diseases such as chickenpox or shingles (brivudine, sorivudine) or if you have taken these medicines in the past 4 weeks. These medicines may increase the activity of this medicine, increasing the risk of side effects (see section 4, "Side effects").

Pregnancy, breastfeeding and fertility
Pregnancy
Do not use **Efudix Cream 5%** and consult your physician if you are pregnant or if you think you might be pregnant.

Females of childbearing potential must use an effective method of contraception during treatment with **Efudix Cream 5%** and for 7 months after treatment.
Males (or their female partners of childbearing potential) must use an effective method of contraception during treatment with **Efudix Cream 5%** and for 4 months after treatment.
If you become pregnant during treatment, inform your physician immediately and make use of genetic counseling.

Breastfeeding
Do not use **Efudix Cream 5%** and consult your physician if you are breastfeeding. If use of the medicine during the period of breastfeeding is absolutely necessary, breastfeeding must be discontinued.

Fertility
The use of **Efudix Cream 5%** may impair fertility in men and women. The use of the medicine is not recommended in men attempting to have children.

Driving and operating machinery
It is unlikely that the medicine will affect your ability to drive or operate machinery.

Important information about some of the medicine's ingredients
Efudix Cream 5% contains ingredients that can cause side effects:
- **Stearyl alcohol** may cause skin irritation (e.g., contact dermatitis - an inflammatory condition of the skin).
- **Propylene glycol** may cause skin irritation. Because the medicine contains this ingredient, do not use on open wounds, on large areas of the body or on damaged skin (e.g., burns) without consulting your physician or pharmacist.
- **Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)**, which may cause allergic reactions (possibly delayed).

Do not use **Efudix Cream 5%** if you are allergic to any of its ingredients.

3. How should you use the medicine?
Always use this medicine according to your physician's instructions. You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen of the medicine.
If you think that the activity of this medicine is too strong or too week, inform your physician and do not change the dosage without consulting your physician.

How to apply

* For external use only.
* Apply **Efudix Cream 5%** to skin only, avoiding contact with the eyes and mouth.
* Apply a thin layer of the cream to the affected area as instructed by your physician.
* It is very important that you do not apply an amount larger than what your physician has recommended and do not apply the cream to open wounds. This may lead to some of the medicine being absorbed into the bloodstream which, very rarely, can cause side effects.

The dosage and treatment regimen will be determined by your physician only. **The usual dosage** is generally:

* Apply a thin layer of **Efudix Cream 5%** to the affected area, 1-2 times a day for at least three to four weeks.
* Wash your hands thoroughly after using **Efudix Cream 5%** (except for when the hands are the treated area).
* Your physician will instruct you if you need to apply a dressing to the treated area.
* The maximum area of the region treated at any one time is 23 X 23 cm (approximately the size of a plate). Larger areas will be treated in separate parts each time.

Do not exceed the recommended dose. Adhere to the treatment regimen as recommended by your physician.

If you accidentally swallowed Efudix Cream 5%, consult your physician or pharmacist immediately, or go directly to a hospital emergency room, and bring the package of this medicine with you.

If the cream accidentally gets in your eyes, mouth or nose, or if someone else uses it, wash the cream off with water and immediately consult your physician or pharmacist, or go to a hospital emergency room, and bring the package of this medicine with you.

If you forget to apply the medicine at the required time, apply the cream as soon as you remember. If it is nearly time to apply the next dose, skip the missed dose and continue with the next dose as part of the routine treatment. Do not apply a double dose to make up for the forgotten dose. Apply the next dose at the regular time and consult your physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. **Wear glasses if you need them.**

If you have additional questions regarding the use of the medicine, consult your physician or pharmacist.

4. Side effects

As with any medicine, the use of **Efudix Cream 5%** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Important information about treatment with **Efudix Cream 5%**

Efudix Cream 5% destroys cancerous and precancerous cells, while having little effect on normal cells.

When you use **Efudix Cream 5%**, it is likely that the area of skin that you are treating will become red. This may 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 Cream 5%** is working.

Sometimes the response is more severe. If your skin becomes much worse, you experience pain, or you are worried, consult your physician. Your physician may prescribe you another cream to relieve the discomfort.

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

Efudix Cream 5% will also treat abnormalities of the skin that were previously not visible to the naked eye, and these abnormalities may become red and inflamed.

Consult your physician immediately if you experience any of these side effects:

- If you experience abdominal pain or other abdominal problems such as: cramps, diarrhea or vomiting.
- If you experience swelling or soreness of the mouth and tongue.
- If you have a fever or feel generally unwell.

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

Additional side effects:

Very rare side effects - effects that occur in fewer than 1 in 10,000 users:

- Side effects related to the skin and subcutaneous tissue: itching, redness, burning sensation, severe peeling, severe swelling or inflammation, ulceration, blistering, irritation, pain, hives and rash. In general, these effects are 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 in areas where cream was not applied
- Hair loss

Side effects whose frequency is not known (effects whose frequency has not yet been determined):

- Painful and/or watering eyes
- Taste disturbance
- Headache, dizziness, nausea
- Bleeding in the treated area

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" on the Ministry of Health homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use this medicine after the expiry date (exp. date) which appears on the outside of the package and tube. The expiry date refers to the last day of that month.

Storage conditions:

- Store at a temperature below 30°C.
- Use within three months of opening.
- 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. Additional information

- Each tube contains: 20 grams of *5% w/w* fluorouracil
- In addition to the active ingredient fluorouracil, the medicine also contains:
  white soft paraffin, stearyl alcohol, propylene glycol, polysorbate 60, methyl parahydroxybenzoate, propyl parahydroxybenzoate, purified water
- What the medicine looks like and the contents of the package: **Efudix Cream 5%** is an opaque white cream marketed in a 20 gram tube.

- **Registration holder and address:** MegaPharm Ltd., 15 Hatidhar St., Ra'ananna, Israel.
- **Manufacturer and address:**
  ICN POLFA RZESZOW S.A., POLAND
  2 PRZEMYSLOWA ST., 35-959 RZESZOW, POLAND

- Updated in May 2023 in accordance with Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  062 40 21478.

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