



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Efudix Cream 5%

Each gram of cream contains 50 mg fluorouracil.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if you think that their illness is similar to yours.

1. What is the medicine intended for?

Efudix is used for the treatment of skin problems, such as keratosis and Basal Cell Carcinoma.

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

Important information regarding treatment with Efudix

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

When you use **Efudix**, the area of skin you are treating is likely to become red. This may be followed by inflammation/swelling, possibly a little discomfort, skin erosion, and eventually healing. This is the expected normal reaction to treatment, and it indicates that **Efudix** is working.

Sometimes the reaction is more severe. If your skin problem worsens significantly, if you experience pain or if you are concerned, refer to your doctor. The doctor may prescribe you another cream to relieve the discomfort.

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

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

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (fluorouracil), or to any of the other ingredients this medicine contains (see section 6).
- You are pregnant, think you may be pregnant or are breastfeeding.
- You are using medicines called 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 the treatment with Efudix, tell the doctor if:

- You suffer from reduced or lack of activity of the enzyme DPD (dihydropyrimidine dehydrogenase) (complete or partial deficiency of the enzyme).

Special caution is required during treatment with Efudix when:

- You apply the medicine on the area of the eyelids, nose or lips. Avoid contact of the medicine with the eyes or mouth (see section 3).

- You have open wounds. Do not use this medicine for treatment of open wounds. This may cause increased absorption of the medicine into the blood which, very rarely, may cause side effects.
- You have ulcerated or inflamed skin. Do not use this medicine on ulcerated or inflamed skin. This may cause increased absorption of the medicine into the blood and may very rarely cause side effects.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bed linen, dressings, etc.) that comes in contact with this preparation burns more easily and poses a serious fire hazard. Washing clothes and bed linen can decrease the accumulation of the preparation, but not remove it completely.

During use of **Efudix**, avoid direct exposure to sunlight as much as possible, and completely avoid tanning lamps and beds, as these increase the effect of **Efudix** and may increase skin reactions.

Avoid exposure to ultraviolet radiation (UV, for example: natural sunlight, tanning salon). Adhesive bandage or dressing may increase the inflammatory reaction of the skin.

Children and adolescents

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

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is **very important** as using more than one medicine at the same time may increase or weaken the effect of the medicines involved.

Tell your doctor especially if you are taking:

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

Pregnancy, breastfeeding and fertility

Pregnancy

Do not use **Efudix** and refer to your doctor if you are pregnant or if you think you may be pregnant.

Women of childbearing age must use an effective contraceptive during treatment and for 6 months after treatment with **Efudix**.

Men (or their female partners of childbearing age) must use an effective contraceptive during treatment and for 3 months after treatment with **Efudix**.

If you become pregnant during treatment, inform your doctor immediately and seek genetic counseling.

Breastfeeding

Do not use **Efudix** and refer to your doctor if you are breastfeeding. If use during breastfeeding is absolutely necessary, breastfeeding must be discontinued.

Fertility

The use of **Efudix** may impair fertility in women and men. The use of the medicine is not recommended in men attempting to father a child.

Driving and using machines

The medicine is not likely to affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Efudix contains:

- **Stearyl alcohol:** may cause a local reaction (such as Contact dermatitis).
- **Propylene glycol:** may cause skin irritation. Since the medicine contains this ingredient, do not use on open wounds or on a large area of damaged skin (such as burns) without consulting your doctor or a pharmacist.
- **Polysorbate 60, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216):** may cause allergic reactions (possibly delayed).

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

If you think that the activity of the medicine is too strong or too weak, refer to your doctor. Do not change the dosage without consulting your doctor.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is:

Application of a thin layer of **Efudix** to the affected area 1-2 times a day for at least three to four weeks.

Do not exceed the recommended dose.

Method of use

- Apply **Efudix** on the skin only and avoid contact of the medicine with the eyes or mouth.
- Apply a thin layer of the cream to the affected area as instructed by your doctor.
- It is **very important** not to apply an amount larger than that recommended to you by the doctor and not to apply the cream on open wounds. This may lead to some of the medicine being absorbed into the blood and, very rarely, this can cause side effects.
- Wash your hands thoroughly after applying **Efudix**.
- The doctor will instruct you if you need to dress the treated area.
- The maximum area to be treated each time is 23 cm X 23 cm (approximately the size of a plate).

If you accidentally swallow Efudix

Immediately refer to your doctor, pharmacist or a hospital emergency room and bring the medicine package with you.

If the cream accidentally gets in your eyes, mouth or nose or if someone else used it

Wash the cream off with water and **immediately** refer to your doctor, pharmacist or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to apply the medicine at the designated time, apply the cream as soon as you remember. If it is almost time for applying the next dose, skip the forgotten dose and continue use at the scheduled times. Do not apply a double dose to compensate for the forgotten dose.

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 further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Efudix** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if you experience any of the following effects, as these can be signs of an allergic reaction:

- Stomach problems such as: pain, cramps, diarrhea or vomiting.
- Swelling or soreness of the mouth and tongue.
- Fever or feeling generally unwell.

These effects may occur if you use too much cream or if you apply the cream on open wounds.

Additional side effects:

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Side effects related 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 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 has not been applied
- Hair loss
- Change in the levels of blood cells
- Bloody diarrhea

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

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

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 the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 30°C.
- After first opening, the product may be used for 3 months.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Purified water, white soft paraffin, stearyl alcohol, propylene glycol, polysorbate 60, methyl parahydroxybenzoate, propyl parahydroxybenzoate.

What the medicine looks like and what the package contains:

Efudix contains an opaque white cream.

Approved package size: 20 gram tube.

Revised in August 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

062-40-21478-00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel