

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Efudix?

Efudix contains the active ingredient fluorouracil. Efudix is used to treat solar keratoses, also known as actinic keratoses or sunspots and Bowen's disease (type of skin cancer)

For more information, see Section [1. Why am I using Efudix?](#) in the full CMI.

### 2. What should I know before I use Efudix?

Do not use if you have ever had an allergic reaction to fluorouracil or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Efudix?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Efudix and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Efudix?

Carefully follow all directions given by your doctor or other healthcare professionals.

- Apply Efudix once or twice daily as advised by your doctor.

More instructions can be found in Section [4. How do I use Efudix?](#) in the full CMI.

### 5. What should I know while using Efudix?

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Efudix.</li><li>• Limit your exposure to sun during and</li></ul>

	<p>immediately following treatment with Efudix.</p> <ul style="list-style-type: none"> <li>● Apply a broad-spectrum sunscreen every day before going outdoors, and regularly reapply during the day, except directly on the treatment area.</li> <li>● If you become pregnant while using Efudix stop using it and tell your doctor immediately.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not let Efudix come into contact with the eyes, eyelids, nostrils or mouth. Efudix is highly irritating to skin and the eyes.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Keep Efudix in a cool dry place where the temperature stays below 30°C and protect from heat.</li> <li>● Keep out of reach of children and pets.</li> </ul>

For more information, see Section [5. What should I know while using Efudix?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include soreness and pain, itchiness or irritation, darkening or reddening of the skin, burning, crusting,

increased sensitivity of the skin to the sun, rash, dermatitis, and scarring.

Serious side effects include stomach problems such as severe pain, cramps, bloody diarrhoea and vomiting, swelling and soreness of the mouth and tongue, fever and chills, or severe pain or ulceration at the site of application.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Efudix®

**Active ingredient:** *Fluorouracil*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Efudix. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Efudix.**

**Where to find information in this leaflet:**

- [1. Why am I using Efudix?](#)
- [2. What should I know before I use Efudix?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Efudix?](#)
- [5. What should I know while using Efudix?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Efudix?

**Efudix contains the active ingredient fluorouracil.**

Efudix belongs to a group of anti-cancer medicines that are applied to the skin. It works by destroying precancerous and cancerous cells, while having little effect on normal cells.

**Efudix is used to treat the following skin conditions:**

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- **Solar keratoses, also known as actinic keratoses or sunspots.**
- **Bowen's disease (type of skin cancer).**

Solar keratoses are rough, red, scaly, or crusty spots on the skin that are caused by too much exposure to sunlight. They are more common on sun-exposed areas, such as the face, nose, ears, chest, forearms, and back of the hands.

Solar keratoses are usually harmless, but there is a small risk that they may eventually turn into skin cancer.

Bowen's disease causes one or more small patches of scaly red skin. It occurs when there is a growth of abnormal cells in the outer layer of skin. It is most commonly found on the lower leg.

## **2. What should I know before I use Efudix?**

### **Warnings**

#### **Do not use Efudix if:**

- You are allergic to fluorouracil, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have a dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.

## **Check with your doctor if you:**

- Have any other medical conditions including inflammatory skin conditions such as darkening of skin during pregnancy (chloasma) or a chronic rash (rosacea).
- Work outside for long periods of time during the day. Exposure to UV radiation from the sun or tanning salons may increase the intensity of skin reactions at the sites where Efudix is applied.
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Do not use Efudix if you are pregnant or intend to become pregnant. Efudix may affect your developing baby if you use it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Nursing mothers should avoid using Efudix as it is not known if the active ingredient in Efudix passes into breast milk, and if there is a possibility that your baby may be affected.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Efudix and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Efudix.**

### **4. How do I use Efudix?**

#### **How much to use**

Apply Efudix to the affected skin once or twice daily as advised by your doctor.

**Follow the instructions below and use Efudix until your doctor tells you to stop.**

- Wash the skin to be treated using lukewarm water. Avoid soap or other cleansing products which may sting or irritate your skin, especially as treatment progresses.
- Pat dry the affected area with a soft white paper towel.
- Allow 15 minutes for your skin to completely dry.
- Using a non-metal applicator, cotton bud or a rubber glove apply a thin film of Efudix, smoothing it gently onto your affected skin. Do not use too much cream.



- Be very careful not to allow Efudix to come into contact with mucous membranes, such as eyes, eyelids, nostrils and lips.
- Do not apply Efudix to broken skin or open cuts as it may be absorbed into the bloodstream and may cause side effects.
- Wash your hands carefully and thoroughly immediately after using Efudix.
- Do not cover the treated area unless your doctor tells you to.
- If your doctor asks you to apply a dressing after using Efudix, apply a fresh dressing to the area(s) daily.
- The total area of skin treated with Efudix at any time should not exceed 500 sq cm (approx. 23 cm x 23 cm). Treat larger areas a section at a time.

## **When to use Efudix**

- Apply in the morning and then again in the late afternoon or early evening.
- Do not apply Efudix immediately before going to bed.
- Apply Efudix at least 1.5 - 2 hours before bedtime to enable complete absorption and prevent wiping off onto pillowcases and sheets. Contact with pillowcases or sheets may result in undesirable spreading of Efudix to normal skin that does not need treatment.

## **How long to use Efudix**

Unless your doctor tells you to stop using Efudix continue treatment up until the ulceration stage, usually 3 to 4 weeks. The healing process is usually complete 1

to 2 months after the end of treatment. The healthy skin surrounding the treated area may occasionally become reddened but will soon resume its normal colour once treatment is stopped.

## **If you forget to use Efudix**

Efudix should be used regularly at the same time each day.

**If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and apply your next dose when you are meant to.**

**Do not try to make up the dose you missed by applying more the next time.**

## **If you use too much Efudix**

If you think that you have used too much Efudix, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using Efudix?**

### **What you should expect**

Expect your appearance to look worse and to feel uncomfortable while treatment is in progress.

Sometimes it can take several weeks after treatment with Efudix has stopped before you see any improvement in your condition.

When Efudix is applied to the skin, the following usually happens:

- Redness of the affected area occurs (generally within 3 to 5 days).
- This is followed by blistering, peeling, and cracking (within 11 to 14 days) with occasional open sores and some discomfort.
- The treated skin will then flake away.
- Some redness of the skin will continue for some time after Efudix is stopped. Scarring is not expected.

### **Things you should do**

- Limit your exposure to sun during and immediately following treatment with Efudix.

This will help reduce the likelihood and severity of unwanted side effects.

- Apply a broad-spectrum sunscreen (SPF 30 or higher) every day before going outdoors, and regularly reapply during the day, except directly on the treatment area.

Efudix can make you more sensitive to sunlight. In addition to sunscreen, wear wide-brimmed hat, long sleeves, and trousers (or a long skirt) to protect your skin.

### **Call your doctor straight away if you:**

- Become pregnant while using Efudix.

Remind any doctor, dentist or pharmacist you visit that you are using Efudix.

### **Things you should not do**

Do not let Efudix come into contact with the eyes, eyelids, nostrils or mouth. Efudix is highly irritating to sensitive skin and the eyes.

### **Do not allow pets to contact the Efudix container or your skin where Efudix has been applied.**

Safely discard or clean any cloth or applicator that may retain Efudix and avoid leaving any residues of Efudix on your hands, clothing, carpeting or furniture. Efudix may be fatal if ingested by pets.

### **Things to be careful of**

**While treatment is in progress follow these personal care tips:**

- Avoid using cosmetics or other topical medications, including sunscreens, directly on the treatment area, unless directed by your doctor.

Your treated skin is expected to become irritated and uncomfortable whilst using Efudix. Applying other products directly on the treatment area may make your discomfort worse.

- You may continue to shave whilst using Efudix but take care not to cut your skin in the treatment area.

As facial skin becomes inflamed during Efudix treatment shaving with a conventional razor may become unpleasant. You may prefer instead to lightly shave with an electric razor or clip the facial hair.

## **Looking after your medicine**

Store below 30°C. Protect from heat.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children and pets cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use Efudix after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

During treatment with Efudix expect to have a temporary unsightly appearance and discomfort at the sites where you apply the cream.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● soreness and pain</li><li>● itchiness and irritation</li><li>● darkening or reddening of the skin</li><li>● burning</li><li>● crusting</li><li>● increased sensitivity of the skin to the sun</li><li>● rash</li><li>● dermatitis</li><li>● scarring.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Stomach problems such as severe pain, cramps, bloody diarrhoea and vomiting</li><li>• Swelling and soreness of the mouth and tongue</li><li>• Fever and chills.</li></ul>	<b>Discontinue Efudix immediately and call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Efudix contains

<b>Active ingredient (main ingredient)</b>	fluorouracil 5 %w/w
<b>Other ingredients (inactive ingredients)</b>	methyl hydroxybenzoate soft white paraffin polysorbate 60 propyl hydroxybenzoate propylene glycol stearyl alcohol purified water
<b>Potential allergens</b>	methyl hydroxybenzoate propyl hydroxybenzoate

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Efudix looks like

Efudix is a white cream that comes in a 20 g aluminium tube (AUST R 13721).



## **Who distributes Efudix**

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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