APO-Imiquimod Cream

Contains the active ingredient imiquimod

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.
This leaflet answers some common questions about imiquimod. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Imiquimod. It contains the active ingredient imiquimod.

It is used to treat:

- Solar keratosis on the face and scalp.
  Solar keratosis is thickened, scaly patches of skin caused by too much sun exposure. It is also known as actinic keratosis.
- Superficial basal cell carcinoma (a type of skin cancer).
- External genital/perianal warts (condyloma acuminate). They appear on the surface of the penis or vulva (external female sexual organ) and around the anus.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Imiquimod is an immune response modifier. It activates immune cells in the body. The immune cells then proceed to kill and remove the virus-infected or cancer cells.

Although the exact way that imiquimod works is unknown, it is believed to be due to its effects on the immune system.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in patients under the age of 18 years.

Before using this medicine

When you must not use it

Do not use this medicine:

- **If you are allergic to, or have had an allergic reaction to, imiquimod or any of the ingredients listed at the end of this leaflet.**
  Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hay fever-like symptoms.
  If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital
- **On skin where there are open sores or wounds. Do not start using imiquimod cream until after the area has healed.**
- **On warts inside the vagina or inside the anus or inside the urethra (where you pass urine). The use of imiquimod cream on these areas has not been studied.**
- **On areas that are sunburnt**
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to use it

Before you start using this medicine, tell your doctor if:

1. You have allergies to:
- any other medicines
- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
- sun damaged skin
- open sores, wounds or broken skin
- inflammatory skin conditions
- autoimmune conditions
- organ transplant
- you are or you think you are HIV positive
3. You have previously used imiquimod cream or other similar preparations to treat your condition.
4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
5. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.
9. You have problems with your immune system.
10. You have an abnormal blood count.
11. You currently have, or in the past have had, any other medical conditions.

Some medicines may interact with imiquimod. These include:

- immunosuppressive medication
- medicines containing methyl hydroxybenzoate, propyl hydroxybenzoate, cetyl alcohol or stearyl alcohol.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with imiquimod.

How to use this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to use

Your doctor will tell where to apply imiquimod cream, how often and for how long to apply it for your condition. This will depend on your condition and whether you are taking any other medicines. Imiquimod cream should be applied just before bedtime and left on the skin for 6-10 hours. Sufficient cream should be applied to cover the treatment area. Talk to your doctor if your condition re-appears after

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Solar Keratosis
If your doctor has prescribed this medicine for the treatment of Solar Keratosis, the usual dosage is once a day, at bedtime, three times a week. For three times a week application, it can be applied, for example, on Monday, Wednesday and Friday, or Tuesday, Thursday and Saturday.

- Your doctor may tell you to continue applying this medicine for 4 weeks, followed by a period of 4 weeks without any treatment. Your doctor will then check your skin condition. If any Solar Keratosis lesions remain, the treatment should be repeated for another four weeks.
- Alternatively, your doctor may want you to continue applying this medicine for up to 16 weeks, Each treatment should continue for no more than 16 weeks at a time.

Superficial Basal Cell Carcinoma
If your doctor has prescribed this medicine for the treatment of Superficial Basal Cell Carcinoma, it should be applied to the affected area once a day at bedtime for five consecutive days per week (Monday to Friday), or as recommended by your doctor. Treatment should continue for 6 weeks unless your doctor tells you otherwise.

External Genital or Perianal Warts
If your doctor has prescribed this medicine for the treatment of external genital or perianal warts, it is to be applied once a day, at bedtime, three times a week or as recommended by your doctor.

For three times a week application, this medicine can be applied on Monday, Wednesday and Friday; or Tuesday, Thursday and Saturday. Treatment should continue until the warts are completely gone. This medicine should not be used for more than 16 weeks at a time. It usually takes 8-10 weeks for your warts to disappear, but warts may clear as early as 4 weeks. If your warts reappear, talk to your doctor.

If your skin reacts badly to this medicine, your doctor may recommend that you stop treatment for a few days. It is not necessary to make up the doses that you missed or to prolong the treatment period.

How to use it

Apply the cream as per your doctor's instructions.

Imiquimod cream is provided in single use sachets. A new sachet should be opened for each treatment,

and cream from a previously opened sachet should not be used.

One sachet contains enough cream to cover a treatment area of 20 square centimetres (approximately 3 square inches).

1. Before applying the cream, wash your hands and the treatment area with mild soap and water and allow the area to dry thoroughly.
2. Open a sachet of imiquimod cream and squeeze some cream onto your fingertip. Apply a thin layer of cream onto the treatment area and rub it gently into the skin until it is no longer visible.

   Sufficient cream should be applied to cover the treatment area.

   For treatment of superficial basal cell carcinoma, enough cream should be applied to cover the lesion and about 1cm of surrounding skin.
3. The cream is to be applied to the affected area prior to normal sleeping hours and should be left on the skin for approximately 8 hours (6-10 hours). During the 6-10 hours treatment period, showering or bathing should be avoided.
4. Carefully dispose of the unused imiquimod cream in the sachet where children cannot reach it. Wash your hands with mild soap and water.
5. Following the treatment period, the cream should be removed by washing the treated area with mild soap and water.

Hand washing before and after cream application is recommended.

Contact with the eyes, ears, lips, nostrils and hairline should be avoided.

The cream should not be applied to the affected area more than once a day.

How long to use it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to use it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.
This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you use too much imiquimod cream (overdose)

Using too much imiquimod cream could cause severe skin reactions. If too much cream is applied, simply wash away the extra cream with mild soap and water. When any skin reaction has settled, you may then continue with your treatment.

If you think that you or anyone else may have used too much of this medicine, or this medicine has been accidentally swallowed, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using this medicine

Things you must do

Stop using this medicine if you become pregnant, and do not use it if you are breastfeeding. Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Do not use more than the recommended amount of imiquimod cream. A thin layer that completely covers the treatment area and surrounding skin is enough
- Do not cover the treatment area with bandages or other dressings after you have applied imiquimod cream. Cotton gauze dressings are okay to use, if needed.

If you are using this medicine to treat solar keratosis:

- Imiquimod cream should not be applied in or near the eyes, lips or nostrils.
- Do not use sunlamps or tanning beds, and avoid going into the sun as much as possible during treatment with imiquimod cream. Wear protective clothing if you go outside during daylight.
- New solar keratosis lesions may develop during treatment with imiquimod cream. These lesions may resolve during the treatment period. Even though the initial solar keratosis lesions may clear with treatment, new lesions may develop in the future and require further treatment. Imiquimod cream is not a cure, since solar keratosis is considered to be a chronic skin condition.
- There is not enough data to support the use of imiquimod cream to treat solar keratosis on the hands and arms.
- Imiquimod cream should not be applied to an area greater than 25 square centimetres.

If you are using imiquimod cream to treat superficial basal cell carcinoma:

- Imiquimod cream should not be applied in or near the hairline, eyes, ears, nose or lips.
- Do not use sunlamps or tanning beds, and avoid going into the sun as much as possible during treatment with imiquimod cream.
- Wear protective clothing if you go outside during daylight.
- Visit your doctor regularly if you are treating more than one superficial basal cell carcinoma lesion at the same time.

If you are using imiquimod cream to treat genital warts:

- Avoid sexual (genital, anal or oral) contact. If you decide to have sexual relations, apply imiquimod cream after, not before, sexual activity. If you have already applied the cream, it should be washed off before sexual activity.
- Imiquimod cream may weaken condoms and diaphragms; therefore, the cream should be washed off before using a condom or diaphragm during sexual activity. Alternate forms of contraception should be considered.
- The effect of imiquimod cream on the transmission of genital warts is not known.
- Uncircumcised men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If daily washing under the foreskin is not carried out, tightness of the foreskin may occur. Early signs of tightness include swelling and wearing away of the skin, or difficulty in pulling back the foreskin. If these symptoms occur, stop the treatment immediately and call your doctor.
- Female patients should take special care if applying imiquimod cream at the opening of the vagina because local skin reactions on the delicate moist surfaces can result in pain or swelling, and may cause difficulty in passing urine.
- Do not use imiquimod cream for more than one course if you have problems with your immune system either due to illness or because of the medicines you are already taking. If you think this applies to you, talk to your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking imiquimod cream or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

More common side effects of imiquimod cream

Tell your doctor if you notice any of the following:

- Application site reactions including: redness, wearing away of the skin, flakiness, swelling, hardening under the skin, small open sores, crust that forms during healing, small bubbles under the skin, itching, burning, pain, tenderness, irritation, rash, soreness, stinging, sensitivity, skin colour becomes lighter, bleeding, lumps on the skin, infection and pimples.
  Most of these skin reactions are mild to moderate, and are signs that the product is working.
  If your skin reacts badly or the skin reaction becomes too uncomfortable when using imiquimod cream, wash the cream off with mild soap and water and contact your doctor.
  Your doctor may recommend that you stop treatment for a few days.
- Flu symptoms, tiredness, fever, headache, diarrhoea, back pain, muscle pain, and swollen glands in the neck, armpit and groin.
- Some patients have experienced changes in skin colour (lighter or darker) in the area where imiquimod cream was applied. These changes may be permanent in some cases.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to imiquimod, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Do not freeze.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Imiquimod looks like

APO-Imiquimod is a white, soft cream, packed in a single-use foil sachet.

Each sachet contains 250 mg of APO-Imiquimod cream, which is enough to cover a treatment area of 20 cm squared.

APO-Imiquimod cream is available in boxes of 1, 3, 6, 12 and 30 sachets*.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each 250 mg of APO-Imiquimod 50 mg/g (5% w/w) cream contains 12.5 mg of imiquimod, as the active ingredient.

APO-Imiquimod cream also contains the following inactive ingredients:

- isostearic acid
- benzyl alcohol
- cetyl alcohol
- stearyl alcohol
- white soft paraffin
- sorbitan monostearate
- polysorbate 60
- xanthan gum
- glycerol
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- purified water.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Imiquimod 50 mg/g (5% w/w) cream:

AUST R 168101.

Sponsor

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