

Apo-Imiquimod

imiquimod

5% w/w cream

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Imiquimod.

This leaflet answers some common questions about Apo-Imiquimod. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Imiquimod is used for

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

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.

Apo-Imiquimod is used to treat solar keratosis (SK) on the face and scalp, superficial basal cell carcinoma (sBCC), and genital/perianal warts.

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

Your doctor may have prescribed Apo-Imiquimod for another reason.

Ask your doctor if you have any questions about why Apo-Imiquimod has been prescribed for you.

Apo-Imiquimod is not recommended for use in patients under the age of 18 years as there have been no studies of its effects in this age group.

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

There is no evidence that this medicine is addictive.

Before you use Apo-Imiquimod

When you must not use it

Do not use Apo-Imiquimod:

- **If you are hypersensitive 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 and wounds. Do not start using imiquimod 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 Apo-Imiquimod cream on these areas has not been studied.**
- **On areas that are sunburnt**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**
- **After the “use by” date shown on the box or sachet.**

If you are not sure whether you should start using Apo-Imiquimod, talk to your doctor.

Before you start to use it

Tell your doctor if:

- **You have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- **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.
- **You are currently breast-feeding or you plan to breast-feed.** Do not take this medicine whilst breast-feeding until you and your doctor has discussed the risks and benefits involved.
- **You are or you think you are HIV positive.**
- **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.
- **You have previously used imiquimod cream or other similar preparations to treat your condition.**
- **You have problems with your immune system.**
- **You have abnormal blood count.**
- **You currently have, or in the past have had, any other medical conditions.**

If you have not told your doctor about any of the above, tell them before you start using Apo-Imiquimod.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Imiquimod.

Some medicines may interfere with Apo-Imiquimod. These include:

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

These medicines may be affected by Apo-Imiquimod, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Imiquimod.

How to use Apo-Imiquimod

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

Apo-Imiquimod is used to treat several skin conditions. Your doctor will tell you where to apply Apo-Imiquimod cream, how often and for how long to apply it for your condition and whether you are taking any other medications. Apo-Imiquimod 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 treatment.

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

When 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).

The dosing frequency of Apo-Imiquimod is different for each indication.

Solar Keratosis

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

- Your doctor may tell you to continue applying imiquimod cream for 4 weeks, followed by a period of 4 weeks without any treatment. Your doctor will then check your skin condition. If any SK lesions remain, the treatment should be repeated for another four weeks.

- Alternatively, your doctor may want you to continue applying imiquimod cream 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 imiquimod for the treatment of sBCC, 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 imiquimod 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, imiquimod can be applied on Monday, Wednesday and Friday; or Tuesday, Thursday and Saturday. Treatment should continue until the warts are completely gone. imiquimod 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 imiquimod, 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 Apo-Imiquimod

1. Before applying the cream, wash the treatment area with mild soap and water and allow the area to dry thoroughly. Open a sachet of Apo-Imiquimod and squeeze some cream onto your fingertip.
2. Apply a thin layer of cream onto the treatment area and rub it gently into the skin until the cream vanishes. For sBCC lesions enough cream should be applied to cover the lesion and about 1cm of surrounding skin.

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

3. If using the sachet after application of the cream, carefully dispose of the unused cream in the sachet where children cannot reach it.
4. Leave cream on the affected area for 6 to 10 hours. Do not shower or bathe during this time.
5. After 6-10 hours, the area where cream was applied should be washed with mild soap and water.

Hand washing before and after cream application is recommended.

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

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

How long to use it

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

Your doctor will advise you when you can stop using Apo-Imiquimod cream.

If you are using imiquimod to treat SK:

- 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 SK lesions may develop during treatment with imiquimod cream. These lesions may resolve during the treatment period. Even though the initial SK lesions may clear with treatment, new lesions may develop in the future and require further treatment. Imiquimod cream is not a cure, since SK is considered to be a chronic skin condition.
- There is not enough data to support the use of imiquimod to treat SK on the hands and arms.
- Imiquimod cream should not be applied to an area greater than 25 square centimeters.

If you are using imiquimod to treat sBCC:

- 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 sBCC lesion at the same time.

If you are using imiquimod to treat genital warts:

- Avoid sexual (genital, anal or oral) contact. If you decide to have sexual relations, apply Apo-Imiquimod cream after, not before, sexual activity. If you have already applied the cream, it should be washed off before sexual activity.
- Apo-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 Apo-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 Apo-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 Apo-Imiquimod 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.

Apo-Imiquimod cream has been prescribed for your use only. Do not give it to anyone else even if you think their condition is the same as yours.

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

If you forget to use it

If you forget a dose, apply the missed dose of cream as soon as you remember and then continue on the regular schedule.

Do not double the dose at any time to make up the missed dose. 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.

While you are using Apo-Imiquimod

Things you must do

Immediately stop using Apo-Imiquimod and check with your doctor if a skin rash or other allergic reaction occurs.

Stop using imiquimod cream if you become pregnant, and do not use if you are breastfeeding.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Apo-Imiquimod.

Use your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are using this medicine.

Tell your doctor (immediately) if you become pregnant while you are using it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep using Apo-Imiquimod.

Always discuss with your doctor any problems or difficulties during or after using Apo-Imiquimod.

Tell your doctor if for any reason, you have not used your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Imiquimod to last weekends and holidays.

Things you must not do

Do not:

- Give Apo-Imiquimod to anyone else, even if they have the same condition as you.
- Use your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- 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.
- Stop using your medicine, or change the dosage, without first checking with your doctor.
- Cover the treatment area with bandages or other dressings after you have applied imiquimod cream. Cotton gauze dressings are okay to use, if needed.

Things to be careful of

Apo-Imiquimod is unlikely to produce an effect on the ability to drive or use machinery.

In case of overdose

If you take too much (overdose)

If the cream is accidentally swallowed, nausea, vomiting, headache, muscle pain and fever could occur. If you or someone else accidentally swallows Imiquimod cream, immediately contact your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Imiquimod.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

More Common Side effects of Imiquimod

The following effects have occurred during clinical trials with imiquimod cream. If the following occur and are severe enough to worry you, tell your doctor.

- 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 adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Imiquimod

Storage

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

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.

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 it 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

Active ingredient:

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

Inactive ingredients:

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

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

Sponsor Details

Apo-Imiquimod is supplied in New Zealand by:

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