

Apo-Ciclopirox

ciclopirox USP

8% w/w Nail Lacquer (Topical Solution)

What is in this leaflet

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

This leaflet answers some common questions about Apo-Ciclopirox. 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-Ciclopirox 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-Ciclopirox is used for

Apo-Ciclopirox contains ciclopirox, which is an antifungal agent. Apo-Ciclopirox is used to treat fungal infections of the nails, caused by dermatophytes, yeasts or moulds, including tinea pedis, tinea cruris and tinea corporis.

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

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

Before you use Apo-Ciclopirox

When you must not use it

Do not use Apo-Ciclopirox if you are allergic to it or any of the ingredients listed at the end of this leaflet. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Apo-Ciclopirox to a child.

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

Do not use it if you are breast-feeding or planning to breast-feed. Apo-Ciclopirox may pass into breast milk and there is a possibility your baby may be affected.

Do not use it after the expiry date (EXP) printed on the pack. If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.

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

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Apo-Ciclopirox is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.

It is not known whether Apo-Ciclopirox passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

Tell your doctor or pharmacist if you plan to have surgery.

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

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-Ciclopirox.

Tell your doctor or pharmacist if you:

- Are a diabetic who needs insulin injections or has diabetic neuropathy (nerve damage caused by diabetes),
- Have a history of immunosuppression (e.g. are currently taking oral corticosteroids, have repeated long-lasting shingles (herpes zoster), have oral or genital herpes (herpes simplex)),
- Are immunocompromised (e.g. received an organ transplant, or are HIV positive),
- Need medicine to control epilepsy,
- Use or require topical corticosteroids every month,
- Use steroid inhalers on a regular basis.

These medicines may be affected by Apo-Ciclopirox, 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-Ciclopirox.

How to use Apo-Ciclopirox

How to use it

1. Before starting treatment, remove any loose nail or nail pieces using nail clippers or nail files. If you have diabetes or problems with numbness in your toes or fingers, talk to your doctor before trimming your nails or removing any nail pieces.
2. Apply Apo-Ciclopirox every other day for the first month (bedtime is best) to all affected nails with the applicator brush provided. Application may be reduced to not less than twice weekly in the second month of treatment and to once weekly from the third month of treatment. Apply Apo-Ciclopirox evenly over the entire nail and the skin right around the nail. Where possible, Apo-Ciclopirox should also be put on the bottom side of the nail and the skin beneath it. This ensures that the nail is saturated with the active ingredient. Let Apo-Ciclopirox dry (about 30 seconds) before putting on socks or stockings. After putting on APO- Ciclopirox, wait 8 hours before taking a bath or shower.
3. Apply Apo-Ciclopirox over the previous coat.
4. Once a week (every 7 days), remove Apo-Ciclopirox with a commercial nail polish remover. Remove as much as possible of the damaged nail using scissors, nail clippers, or nail file.
5. Repeat process (steps 2 through 4).

APO-Ciclopirox may be used up to once daily.

When to use it

If you are not sure when to use it, ask your doctor or pharmacist.

How long to use it

Up to 48 weeks of using APO-CICLOPIROX every other day and having your doctor remove the loose, infected nail as often as monthly is usually how long it takes to get a clear or almost clear nail (which means that 10% or less of your nail is still affected). You may need as long as six months of treatment before you first notice your nail(s) getting better.

Your nail may never become completely clear with this product. In clinical studies, less than 12% of patients finished with either a clear nail or almost clear nail.

Speak to your doctor or pharmacist if there has been no improvement in symptoms after six months.

Ask your doctor or pharmacist if you are not sure how long to use the medicine for.

If you forget to use it

Apply it as soon as you remember, and then go back to using the solution as you would normally.

Do not use a double dose to make up for the dose you have missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for hints.

While you are using Apo-Ciclopirox

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are using Apo-Ciclopirox.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.

If you become pregnant while you are using this medicine, stop using it and tell your doctor or pharmacist immediately.

Things you must not do

Do not put it inside the mouth or vagina.

Do not apply the solution to your eyes.

Never swallow this medicine.

Do not cover the affected area with a bandage after applying the Solution.

Do not use nail polish or other nail cosmetic products on the treated nails.

Do not use more than the recommended dose unless your doctor or pharmacist tells you to.

Do not give Apo-Ciclopirox to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Apo-Ciclopirox without checking with your doctor or pharmacist.

Things to be careful of

This medicine does not usually affect the ability to drive or operate machinery but be careful when driving or operating machinery or participate in any dangerous activities where alertness is required, until you know how this medicine affects you.

Avoid use near heat or open flames because the product is flammable (catches fire easily).

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Ciclopirox.

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Ciclopirox. It helps most people with fungal infections, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you. 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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin irritation, redness or rash around the application area. These are mild side effects of this medicine and usually short-lived.

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-Ciclopirox

Storage

Keep Apo-Ciclopirox in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

Caution

Flammable liquid keep away from heat and flame.

Keep the bottle tightly closed in its carton.

To prevent screw cap from sticking to the bottle, do not allow APO-Ciclopirox to get into the bottle threads.

To prevent Apo-Ciclopirox from drying out, the bottle should be closed tightly after every use.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car. Heat and damp can destroy some medicines.

Keep it 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 using Apo-Ciclopirox, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Apo-Ciclopirox 8% w/w nail lacquer is a clear, colourless to slightly yellowish solution.

Available in 9ml glass bottles containing 6.6ml of solution.

Ingredients

Active ingredient:

- A bottle of solution contains 8% w/w of the active ingredient ciclopirox USP.

Inactive ingredients:

- Monobutyl Ester of Poly (Methyl Vinyl Ether/Maleic Acid) in Isopropyl Alcohol
- Isopropyl Alcohol USP
- Ethyl Acetate NF

This medicine is lactose and glucose free.

Sponsor Details

Apo-Ciclopirox is supplied in New Zealand by:

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32 Hillside Road
Glenfield
Private Bag 102995
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