

Apo-Clotrimazole

3 Day Cream

6 Day Cream

contains the active ingredient, clotrimazole (kloe-TRIM-a-zole)

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 using your medicine. Ask your pharmacist or doctor if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about Apo-Clotrimazole Cream.

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. Some more recent information on your

medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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

Keep this leaflet with the medicine.

You may want to read it again.

What Apo-Clotrimazole is used for

The name of your medicine is Apo-Clotrimazole Cream. It contains the active ingredient, clotrimazole.

Clotrimazole is used to treat the vaginal yeast infection known as Candida. Candida infections of the vagina are commonly referred to as "thrush".

Symptoms of thrush include vaginal discomfort, itchiness and discharge.

How it works

Clotrimazole belongs to a group of medicines called anti-fungals. It works by killing the fungi that cause the Candida infection.

Candida infections result from an imbalance of the natural micro-organisms that are present in the vagina. This then causes an overgrowth of yeast fungus.

Certain conditions may increase the chance of infection:

- diabetes
- obesity
- fatigue
- hormonal changes during pregnancy or during certain times of the menstrual cycle or due to the oral contraceptive pill
- certain medicines, such as antibiotics and steroids.

This medicine may be recommended by a pharmacist without a prescription.

Use in children

This medicine should not be used in children.

Before you use Apo-Clotrimazole

When you must not use it

Do not use this medicine if you have an allergy to:

- any medicine containing clotrimazole
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergy may include rash, itching, burning swelling or redness in the area where the cream has been applied.

Do not use this cream in your eyes.

Do not use this cream after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are unsure whether you should start using this medicine, talk to your pharmacist or doctor.

Before you start to use it

See your doctor if:

1. This is your first course of treatment.
2. You are under 18 years of age
3. You have had three or more infections within the last six months
4. You are pregnant. Your doctor will discuss with you the risks and benefits of using this cream, and may recommend other treatments which don't involve the use of an applicator
5. You have diabetes. Your doctor will check that your sugar levels are under control
6. You have allergies to any other cream, gel or ointment

7. You are breast feeding. It is not known if this medicine passes into breast milk. Your doctor can discuss this with you.

Taking other medicines

There is no evidence that this cream interferes with any other medicines.

As this medicine is available from your pharmacist, you can ask them for further information before you start to use it.

How to use this cream

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or in this leaflet, ask your pharmacist or doctor for help.

How much to use

Use one applicator fully filled with 5 g cream once daily.

Use one applicator each consecutive day.

How to use it

Insert one fully filled applicator into the vagina once daily by following the directions below.

1. Wash your hands thoroughly.
2. Remove the cap from the tube of cream.
3. Screw the open end of the applicator to the tube.
4. Pull the applicator plunger all the way out, until it stops.
5. Squeeze the tube of cream until the applicator is full. (The applicator will then hold approximately 5 g of cream).
6. Unscrew the applicator from the tube and replace the cap on the tube.
7. Lie on your back with your knees bent. Gently insert the applicator (open end first) deep into the vagina.
8. Hold the applicator in position and slowly push the plunger all the way in.
9. Remove the applicator from the vagina and discard it.

Applicators are for single use only.

10. Wash your hands thoroughly.

When to use it

It is best to use this medicine at bedtime, preferably after a bath or shower.

Use it at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

If possible, try to time the treatment so as to avoid your menstrual period.

However, if your period occurs during treatment, the course should be completed.

Avoid using tampons while using this medicine.

How long to use it for

Use this medicine on consecutive days or as directed by your doctor or pharmacist.

Do not stop using this medicine unless your doctor tells you to do so. If you stop using this medicine too soon, your infection may return.

See your doctor if no improvements occur after four days or if the infection returns.

If you forget a dose

Use your medicine as soon as you remember that you have missed a dose.

If it is nearly time for your next dose, wait until then to use the medicine and skip the missed dose.

Do not apply two doses at any time to make up for missed doses.

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

While you are using Apo-Clotrimazole

Things you must do

If you are about to start any new medicine, tell your doctor and pharmacist that you are using Apo-Clotrimazole Cream.

Tell any doctors, dentists and pharmacists who treat you that you are using this medicine.

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

It is important to complete the course of treatment, as incomplete courses may result in your symptoms returning.

Tell your doctor or pharmacist if you have problems with vaginal itching or burning and/or increased vaginal discharge.

If you are sexually active, ask your doctor or pharmacist if it is necessary to treat your partner as well.

Be careful if you are using latex products such as condoms and diaphragms. They may not work as well, since the mineral oil in this cream may weaken them.

This effect is temporary and happens only whilst this cream is still in your vagina.

It is advisable to wait until 72 hours after the last dose of cream before using condoms or diaphragms.

Hygienic Considerations

Maintain strict personal hygiene while using this medicine to avoid the possibility of re-infection.

Wash your hands thoroughly before and after inserting the applicator into the vagina.

In addition to your usual hygiene routine, follow the measures listed below to help prevent re-infection:

- After urinating, use toilet tissue as a blotter; avoid a forward or backward motion.
- When using toilet tissue after a bowel motion, use a wiping motion away from the vagina to avoid the possibility of spreading organisms from the rectum to the vaginal tract.
- Wear only clean cotton underwear.
- Change underwear, night attire, towels and linen daily while using this medicine.

Discard each applicator after use.

Things you must not do

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

Do not give it to anyone else, even if they have the same symptoms as you.

Do not douche or use tampons during the course of your treatment.

Do not wear tight clothing or synthetic underwear.

Loose fitting clothing and cotton underwear will help prevent thrush.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using this cream.

This medicine helps most people with thrush. It is generally well tolerated but 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. You may need medical attention if you get some side 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:

- stinging
- burning
- general irritation.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Symptoms of an allergic reaction (e.g. shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Seek urgent medical advice if this product is swallowed.

After using Apo- Clotrimazole

Storage

Keep your cream in the manufacturer's tube until immediately before use.

If you take your cream out of the tube it may not keep well.

Keep the applicators in the carton until needed. Use the cream immediately once it has been dispensed into the applicator.

Keep Apo-Clotrimazole Cream in a cool dry place, where the temperature stays below 25°C.

Do not store this cream 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 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Clotrimazole looks like

Apo-Clotrimazole 3 Day Cream

is a soft, shiny, white cream.

The tube contains 20 g of cream and comes with 3 single-use disposable applicators.

Apo-Clotrimazole 6 Day Cream

is a soft, shiny, white cream.

The tube contains 35 g of cream and comes with 6 single-use disposable applicators.

Ingredients

Apo-Clotrimazole 3 Day Cream

contains 20 mg/g (2% w/w) of clotrimazole as the active ingredient.

Apo-Clotrimazole 6 Day Cream

contains 10 mg/g (1% w/w) of clotrimazole as the active ingredient.

The creams also contain the following inactive ingredients:

- propylene glycol
- cetomacrogol 1000
- cetostearyl alcohol

- liquid paraffin
- dimethicone 100
- white soft paraffin
- self emulsifying glyceryl monostearate
- benzyl alcohol
- disodium edetate
- purified water

Australian Registration Number

Apo-Clotrimazole 3 Day Cream:

AUST R 150662.

Apo-Clotrimazole 6 Day Cream:

AUST R 150663.

Sponsor

Apotex Pty Ltd

ABN 52 096 916 148

66 Waterloo Road

North Ryde NSW 2113

Australia

Apotex Pty Ltd is the licensee of the registered trade marks, APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was prepared in:

April 2009.