

CANDAZOLE V CREAM

Clotrimazole 2.0% w/w

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

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Candazole V Cream against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Candazole V Cream is used for

Candazole V Cream is indicated for the treatment of vaginal yeast infection (thrush) and relief of associated external vulvar (entrance of the vagina) itching and irritation.

Thrush may cause the following symptoms:

- Vaginal itching
- Vaginal soreness
- A white odourless discharge from the vagina
- Pain during urination

How Candazole V Cream works

This medicine contains Clotrimazole which is a broad spectrum antifungal agent. It permeates the chitin (a characteristic component of the cell walls of fungi) and increases the membrane permeability to various intracellular substances (substances inside the fungal cell). In *Candida albicans*, Clotrimazole inhibits transformation of blastospores (an asexual fungal spore produced by budding) into invasive mycelial form (vegetative part of a fungus, consisting of a mass of branching, thread-like hyphae).

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Candazole V Cream

-When you must not use it

Do not take Candazole V Cream if you have an allergy to:

- Any medicine containing Clotrimazole or the excipients.

Some of the symptoms of an allergy reaction may include swelling, rash, itching or hives on the skin of the area of the body to which treatment has been applied.

If any of the above applies to you, talk to your pharmacist.

-Before you start to use it

Tell your pharmacist or doctor if:

- If you have allergies to any other topical treatments
- If you are pregnant or trying for a baby.

Tell your doctor or pharmacist before using Candazole V Cream. If you have informed your doctor or pharmacist already, follow his/her instructions carefully.

If you are breast-feeding, tell your doctor or pharmacist before using Candazole V Cream as

they will be able to discuss with you the risks and benefits of the treatment.

It is not known whether the active ingredient, Clotrimazole, is excreted in breast milk

-Taking other medicines

Tell your doctor about all the other medicines and skin products you use, including prescribed and non-prescribed medicines, vitamins, herbal supplements, and cosmetics. There is no known of drug interactions with Candazole V Cream have been reported.

How to use Candazole V Cream

-How much to use

Use Candazole V Cream exactly as prescribed by your doctor and pharmacist.

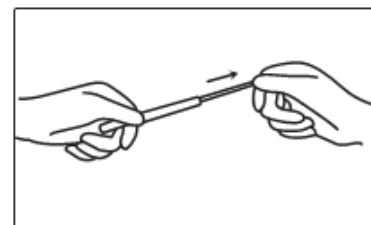
-When to use it

Wash your hands thoroughly before handling the cream or using the applicator. The cream should preferably be inserted in the evening, just before bed time, with the use of an applicator. Using it before you go to sleep will give the best treatment effect. Use a new applicator for each dose.

Guide to use Candazole V Cream:

A) Loading the Applicator

1. Puncture the Candazole V Cream tube seal by using the sharp point of the cap. Screw on the applicator to the tube.

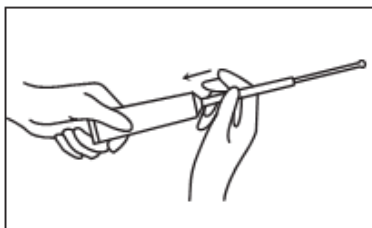


2. Squeeze the cream tube and simultaneously pull on the plunger of the applicator until it stops. (This will fully load the applicator).

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- Remove the loaded applicator from the cream tube and cap back the cream tube.

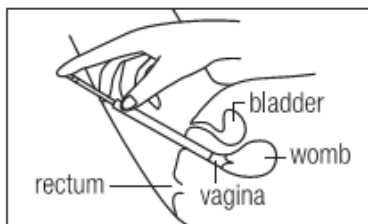


B) Using Candazole V Cream

- Raise one leg about 8-10 inches high (e.g. stepping on a stool) with thighs slightly apart.
- Hold the loaded applicator with the hand opposite to the raised leg. With the body relaxed and slightly bent over, gently insert the applicator into the vagina opening.

C) Inserting the Applicator

- Then gently push up until the applicator meets a firm resistance when it reaches the top of the vagina passage.
- While in this position, gently depress the plunger of the applicator fully to its end. This will deposit all the measured dose of cream deep into the vagina canal.
- Remove the applicator gently from the vagina and dispose in a safe manner.



-How long to use it

For the treatment of vaginal yeast infections. Using the disposable applicator, insert Candazole V Cream once daily, as gently and deeply as possible into the vagina, preferably at bedtime, for 3 consecutive days.

For relief of external vulvar itching, apply a small amount of Candazole V Cream onto affected area twice

daily for up to 7 days. For the prevention of re-infection, the (sexual) partner should be treated locally with Candazole V Cream at the same time even though no symptoms of infection are present.

-If you forget to use it

Use it as soon as you remember. Then go back to your regular schedule. Continue using the cream until the course is finished. The 20g tube contains sufficient cream for 3 doses. Do not make up the missed dose. If you miss several doses, tell your doctor.

-If you use too much (overdose)

If you accidentally take too much go and see your doctor straightaway.

While you are using it

-Things you must do

If irritation or sensitivity occurs, treatment should be discontinued. Consult your doctor if symptoms do not disappear within 7 days, or worsen during the 3 days treatment period.

-Things you must not do

Do not take Candazole V Cream to treat any other areas unless your doctor tells you to.

Do not give your treatment to anyone else, even if you suspect they have the same condition as you.

Do not stop using this medicine until you have completed the course.

If you stop taking it suddenly, your condition may worsen.

-Things to be careful of

For External Use Only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. If condition worsens or does not improve after regular use of this product as directed, consult a doctor.

Side effects

Like all medicines, Candazole V Cream can cause side effects, although not everybody gets them. As with all medicines, some people may be allergic to the cream.

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

- In a small fraction of recipients, Clotrimazole when applied topically may cause abdominal or stomach pain, skin irritation to patient or to the sexual partner.

If any of the above occurs, treatment should be discontinued.

If you notice any side effect even though it is not listed here, please tell your pharmacist or doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Candazole V Cream

-Storage

Store below 30°C. Keep this medicine in a safe place out of reach of children.

-Disposal

Dispose the medicine after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product description

-What it looks like

Candazole V Cream an opaque white viscous cream with characteristic odour containing Clotrimazole 2% w/w and Benzyl Alcohol 1% w/w as preservative.

Candazole V Cream is presented in a screw-cap tube containing 25g of cream.

-Ingredients

-Active ingredient(s):

Each 25g contains 2% w/w of Clotrimazole

-Inactive ingredients:

Benzyl alcohol, Sorbitan monostearate, Octyldodecanol, Cetostearyl Alcohol, Polysorbate 60, Xanthan Gum, Cetyl Palmitate, Glycerin, Purified water.

-MAL number:

MAL09051237AZ

Manufacturer

HOE Pharmaceuticals Sdn. Bhd.
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Product Registration Holder:

HOE Pharmaceuticals Sdn. Bhd.
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