

CANDAZOLE V SINGLE DOSE CREAM

Clotrimazole (10% w/w)

What is in this leaflet

1. What Candazole V Single Dose Cream is used for
2. How Candazole V Single Dose Cream works
3. Before you use Candazole V Single Dose Cream
4. How to use Candazole V Single Dose Cream
5. While you are using Candazole V Single Dose Cream
6. Side effects
7. Storage and Disposal of Candazole V Single Dose Cream
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

This leaflet answers some common questions about Candazole V Single Dose 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 Single Dose 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 Single Dose Cream is used for

Candazole V Single Dose Cream is indicated for the treatment of vaginal yeast infection (thrush) and relief of associated external vulvar 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 Single Dose Cream works

This medicine contains Clotrimazole which is a broad spectrum antifungal agent (chemical that can fight the cause of infection). It inhibits the biosynthesis of ergosterol (a type of sterol that available in animal and plant tissues which convert to vitamin D when exposed to ultraviolet ray) or other sterols, damaging the fungal cell membrane and altering its permeability. 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 Single Dose Cream

- When you must not use it

Do not take Candazole V Single Dose 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 or the parts of the body to which treatment has been applied; rash, itching or hives on the skin.

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 Single Dose 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 Single Dose Cream as they will be able to discuss with you the risks and benefits involved with 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 prescription and non-prescription medicines, vitamins, herbal supplements, and cosmetics. There is no known medicinal interactions with Candazole V Single Dose Cream have been reported.

How to use Candazole V Single Dose Cream

- How much to use

Use Candazole V Single Dose 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 have the best treatment effect.

- How long to use it

For the treatment of vaginal yeast infections, load the disposable applicator full of cream (5g) and insert intravaginally, preferably before bedtime.

For relief of external vulva itching, apply a small amount of Candazole V Single Dose Cream onto affected area twice daily. For the prevention of re-infection, the (sexual) partner should be treated locally with Candazole V Single Dose 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 10g tube contains sufficient cream for 1 dose application. Do not make up the missed dose. If you miss several doses, tell your doctor.

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

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

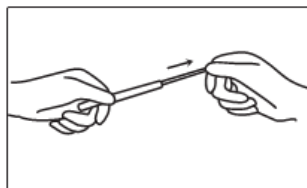
- If you use too much (overdose)

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

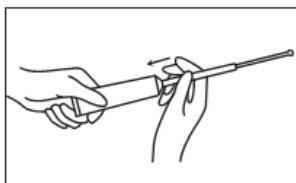
- How to use it

1. Depress the plunger fully into the barrel of the applicator. Remove the cap from the tube,

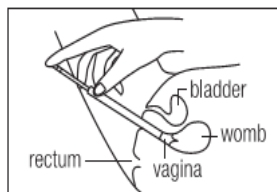
pierce the sealed end of the tube with the back of the cap and attach the applicator onto the tube.



2. Squeeze the tube from the bottom until the applicator is fully loaded (as a single dose of 5g cream). Detach the applicator from the tube.



3. While lying on the back, insert the loaded applicator into the vaginal as far as it will go comfortably. Depress the plunger slowly to deposit the cream into the vagina.



4. Withdraw the applicator and discard it safely from children.

While you are using Candazole V Single Dose Cream

- 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 Single Dose 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

Preferably the treatment should be times to avoid the menstrual period.

Candazole V Single Dose Cream may reduce the effectiveness and safety of latex products, such as condoms and diaphragms.

This effect is temporary and occurs only during treatment.

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.

This preparation contains benzyl alcohol. Its use should be avoided in children under 2 years of age. Do not use in neonates.

Side effects

Like all medicines, Candazole V Single Dose 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:

- Abdominal or stomach pain
- Skin irritation

If any of the above occurs to you or your sexual partner, treatment should be discontinued.

If any side effect becomes severe, or you notice any side effect 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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety.)

Storage and Disposal of Candazole V Single Dose Cream

- *Storage*

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

Do not take the medicine after the expiry date on the label.

- *Disposal*

Dispose the medicine after the expiry date.

Consult your pharmacist on how to safely dispose of any medicines no longer required.

Use by the date on the end flap of the carton.

Product description

- *What it looks like*

Candazole V Single Dose Cream is an opaque off-white viscous cream with characteristic odour.

Candazole V Single Dose Cream is presented in a screw-cap tube containing 10g of cream.

- *Ingredients*

Active ingredient(s):

Each 10g contains 10% w/w of Clotrimazole.

Inactive ingredients:

Benzyl alcohol, Sorbitan monostearate, Cetyl palmitate, Cetostearyl alcohol, Polysorbate 60, Isopropyl myristate, Xanthan gum and purified water.

- *MAL number:* MAL11065001AZ

Manufacturer

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Product Registration Holder

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Date of revision

21/06/2017

Serial Number

BPFK(R4/1)21062017/00143