# CANDAZOLE SOLUTION

Clotrimazole (1% w/v)

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This leaflet answers some common questions about Candazole Solution. 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 Solution 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 Solution is used for

Candazole Solution is used to treat all fungal skin infections due to dermatophytes (fungi that require keratin for growth), yeasts, moulds and other fungi.

#### **How Candazole Solution works** Candazole Solution contains

Candazole Solution contains Clotrimazole as active ingredient.

Clotrimazole is a broad spectrum imidazole anti-fungal agent which fights the cause of fungal skin. Ask your pharmacist or doctor if you have any questions about this medicine.

# Before you use Candazole Solution

-When you must not use it

Do not use Candazole Solution if:

 You are allergic (hypersensitive) to Clotrimazole or to any of the other ingredients in this medicine.

#### -Before you start to use it

Tell your pharmacist or doctor:

 If you are allergic (hypersensitive) to Clotrimazole or to any of the other ingredients in this medicine.

Pregnancy and breast feeding:

- Safe use during pregnancy and lactation has not been established.
- Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.
- A decision must be made whether to discontinue breastfeeding or to discontinue / abstain from Clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

### -Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

### **How to use Candazole Solution**

-How much to use

The solution should be thinly and evenly applied to the affected area 2 or 3 times a day and gently rubbed in.

A few drops are enough to treat an area of about the size of the hand.

There is no separate dosage schedule for the elderly or the young.

#### <u>-When to use it</u>

Use after wash and dry the affected area.

## -How long to use it

To prevent relapse, treatment should be continued for at least 2 weeks after all clinical signs have disappeared.

#### -If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)
No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral

ingestion. There is no specific

antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

# While you are using Candazole Solution

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Candazole Solution.

Attention to hygiene is important in the management of fungal diseases, particularly of the folds and the feet.

# CANDAZOLE SOLUTION

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#### -Things you must not do

Candazole Solution is for external use only. Do not put the solution in your mouth or swallow it. If the solution is swallowed accidently, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. If you accidently get solution in your eyes or mouth, wash immediately with water and contact your doctor.

#### -Things to be careful of

Avoid contact with eyes and mucous membranes (for external use only). Not for ophthalmic (pertaining to the eye) use.

#### **Side effects**

Like other medicines, Candazole Solution can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.

#### Immune system disorders:

 Allergic reaction (fainting, low blood pressure, shortness of breath, hives).

Skin and subcutaneous tissue disorders:

- Blisters
- Discomfort/pain,
- Oedema (fluid retention in the body)
- Erythema (redness of the skin)
- Irritation
- Peeling/exfoliation
- Pruritus (Itching that causes the desire or reflex to scratch)
- Rash
- Stinging/burning.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 Problem / Side Effects / AEFI / Vaccine Safety).

# Storage and Disposal of Candazole Solution

<u>-Storage</u>

Store below 30°C. Keep container well closed. Protect from strong light. Keep 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.

## **Product description**

-What it looks like

Candazole Solution is a translucent, colourless, slightly viscous liquid with a characteristic odour.

Candazole Solution is available in glass bottle of 10ml.

# -Ingredients

-Active ingredient(s): Each 10ml contains Clotrimazole 1%w/v.

-Inactive ingredients: Sodium Hydroxide, Ethylcellulose, Acrylates/Octylacrylamide Copolymer, Purified Water, Alcohol.

### <u>-MAL number:</u> MAL14055164XZ

#### Manufacturer:

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, Malaysia.

### **Product Registration Holder:**

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, Malaysia.

# Date of revision

22/06/2017

#### **Serial Number:**

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