

# CANDID EAR DROPS

Clotrimazole USP 1% w/v

---

## What is in this leaflet

1. What Candid Ear Drops is used for
2. How Candid Ear Drops works
3. Before you use Candid Ear Drops
4. How to use Candid Ear Drops
5. While you are using it
6. Side effects
7. Storage and Disposal of Candid Ear Drops
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Candid Ear Drops is used for

The active substance in Candid 1% Ear Drops is clotrimazole. Clotrimazole belongs to a group of medicines called imidazoles and is an antifungal agent which fights the cause of fungal ear infections.

## How Candid Ear Drops works

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole

at the site of infection. In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides). In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate. Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

## Before you use Candid Ear Drops

### When you must not use it

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

### Before you start to use it

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Candid 1% Ear Drops. If you have informed your doctor or midwife already, follow his/her instructions carefully

### Taking other medicines

Candid 1% Ear Drops and Sofradex drops may cause a heat reaction when used together. Consult your doctor before using these products together in the ear

## How to use Candid Ear Drops

### How much to use

If Candid 1% Ear Drops has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- For ear infections, put 2 - 3 drops of Candid 1% Ear Drops in the ear two or three times daily.
- The treatment should be continued for at least two weeks after the disappearance of all signs of infection, to prevent re-infection. Candid 1% Ear Drops is for external use only

### When to use

To treat fungal infections of the outer and middle ear

### How long to use it

- If Candid 1% Ear Drops has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:
- For ear infections, put 2 - 3 drops of Candid 1% Ear Drops in the ear two or three times daily.
  - The treatment should be continued for at least two weeks after the disappearance of all signs of infection, to prevent re-infection.

### If you forget to use it

Use the drops as soon as possible and then continue the rest of your treatment as usual

*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 it**

*Things you must do*

If Candid 1% Ear Drops has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- For ear infections, put 2 - 3 drops of Candid 1% Ear Drops in the ear two or three times daily.

The treatment should be continued for at least two weeks after the disappearance of all signs of infection, to prevent re-infection

If you get any side effects, talk to your doctor, pharmacist or nurse.

*Things you must not do*

Candid 1% Ear Drops is for external use only:

Do not put the solution in your mouth or swallow it.

If the solution is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

If you accidentally get solution in your eyes or mouth, wash

immediately with water and contact your doctor.

*Things to be careful of*

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Candid 1% Ear Drops. If you have informed your doctor or midwife already, follow his/her instructions carefully

**Side effects**

Like all medicines, Candid 1% Ear Drops can cause side effects, although not everybody gets them. As with all medicines, some people may be allergic to the solution. If you are allergic, a reaction will occur soon after you start using it. If you experience an allergic reaction, stop using Candid 1% Ear Drops and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

Signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

After you use the drops you might experience:

- Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of skin.

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 visiting the website [np.ra.gov.my](http://np.ra.gov.my)

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

**Storage and disposal of Candid Ear Drops**

Store below 30°C. Protect from light.

**Disposal**

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*

A printed carton containing an insert and a labeled LDPE bottle fitted with plug and blue coloured cap containing a clear colourless viscous liquid

*Ingredients*

- Active Ingredients  
Clotrimazole USP

- Inactive ingredients  
Propylene Glycol USP base

*MAL number:*

MAL19900331AZ

**Manufacturer:**

Glenmark Pharmaceuticals Ltd  
Plot No. E-37, 39, D-Road,  
MIDC,  
Satpur, Nashik - 422 007,  
Maharashtra State, India.

**Product Registration Holder**

Glenmark Pharmaceuticals  
(Malaysia) Sdn Bhd (660397-  
W)  
D-31-02, Menara Suezcap 1,  
No. 2, Jalan Kerinchi,  
59200 Kuala Lumpur,  
Malaysia

**Date of revision**

31/01/2022

**Serial number:**

NPRA(R2/1)200707/480