

Applicant: Ranbaxy Pharmaceutical (Pty) Ltd
Product name: Candacide Oral Suspension
Dosage Form: Suspension
Strength: 100 000 iu per ml
Date of Amendment: October 2021



SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

CANDACIDE ORAL SUSPENSION

(Nystatin 100 000 units)

Contains sugar:

Liquid sorbitol: 500 mg/ml

Glycerol: 100 mg/ml

Contains sweetener: Saccharin sodium: 0,5 mg/ ml

Read all of this leaflet carefully because it contains important Information for you

CANDACIDE ORAL SUSPENSION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CANDACIDE ORAL SUSPENSION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CANDACIDE ORAL SUSPENSION with any other person
- Ask your healthcare provider or pharmacist if you need more information or advise.
- You must see a doctor if your symptoms worsen or do not improve.

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What is in this leaflet

1. What CANDACIDE ORAL SUSPENSION is and what it is used for
2. What you need to know before you take CANDACIDE ORAL SUSPENSION
3. How to use CANDACIDE ORAL SUSPENSION
4. Possible side effects
5. How to store CANDACIDE ORAL SUSPENSION
6. Contents of the pack and other information

1. What candacide oral suspension is and what it is used for

CANDACIDE ORAL SUSPENSION contains NYSTATIN and is an antibiotic with antifungal activity against a wide variety of yeasts and yeast like fungi especially the Candida genus

It can be used to:

- Treatment of candidal (monilial) infections of the oral cavity.

2. What you need to know before you take CANDACIDE ORAL SUSPENSION

Do not take CANDACIDE ORAL SUSPENSION:

- If you are hypersensitive (allergic) to nystatin or any of the other ingredients of CANDACIDE ORAL SUSPENSION

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

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Warnings and precautions

Take special care with CANDACIDE ORAL SUSPENSION :

- If you have systemic mycosis as CANDACIDE ORAL SUSPENSION should not be used.
- If irritation or sensitization develops, treatment should be discontinued.
- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before receiving CANDACIDE ORAL SUSPENSION. Do this even if they have applied in the past.

Other medicines and CANDACIDE ORAL SUSPENSION

Always tell your healthcare provider if you or your child is taking any other medicine (this includes all complementary or traditional medicines)

CANDACIDE ORAL SUSPENSION with food and drinks

The intake of food and drinks will have no impact on CANDACIDE ORAL SUSPENSION

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking CANDACIDE ORAL SUSPENSION

Driving and using machines

CANDACIDE ORAL SUSPENSION will have no impact on driving or using machinery

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CANDACIDE ORAL SUSPENSION contain sorbitol and glycerol

CANDACIDE ORAL SUSPENSION contains sorbitol solution (70 %) non crystallising. Sorbitol is a source of fructose. If your doctor has told you or your child have an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you or your child receives CANDACIDE ORAL SUSPENSION.

CANDACIDE ORAL SUSPENSION also contains glycerol.

Glycerol may cause headache, stomach upset and diarrhoea.

3. How to take CANDACIDE ORAL SUSPENSION:

Taking your medicine:

Do not share medicines prescribed for you with any other person.

Always take CANDACIDE ORAL SUSPENSION exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

SHAKE THE BOTTLE BEFORE USE.

INFANTS:

The usual dose is 1 ml to 2 ml (100 000 to 200 000 units) four times daily, dropped into the mouth.

CHILDREN AND ADULTS:

The usual dose is 1 ml to 2 ml (100 000 to 200 000 units) four times daily, dropped into the mouth and held for some time before swallowing. This dose may be increased to 4 ml to 6 ml (400 000 to 600 000 units) four times daily for more severe infections.

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(On administration by dropper, the suspension readily disperses throughout the mouth and is a compatible with commonly used systemic antimicrobial agents and may be given concomitantly with these agents).

The suspension should be retained in the mouth for as long as possible (e.g. several minutes) before swallowing. In infants and young children, apply one half of the dose in each side of the mouth.

The dosage regimen for Candacide Oral Suspension should be continued for at least 48 hours after symptoms have disappeared.

NOTE: If significant regeneration or repair of oral tissue has not occurred in seven days, additional investigation into the etiology of the oral lesion is advised.

If you take more CANDACIDE ORAL SUSPENSION than you should:

Treatment is symptomatic and supportive.

You might experience nausea and gastrointestinal disturbances in the event of taking more CANDACIDE ORAL SUSPENSION than the recommended dosage.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the carton and bottle with you. This is so the doctor knows what you have taken.

If you forget to take CANDACIDE ORAL SUSPENSION:

If you forget to take CANDACIDE ORAL SUSPENSION, take it as soon as you remember.

However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

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4. Possible side effects

CANDACIDE ORAL SUSPENSION can have side effects.

Not all side effects reported for CANDACIDE ORAL SUSPENSION are included in this leaflet.

Should your general health worsen or if you experience any untoward effect while taking CANDACIDE ORAL SUSPENSION, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking/using CANDACIDE ORAL SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital :

- if you get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficult in swallowing or breathing.
- if you could notice an itchy, nettle rash (urticaria). This may mean that you are having an allergic reaction to CANDACIDE ORAL SUSPENSION.
- Fainting

These are all very serious side effects. If your child has them, your child may have had a serious reaction to CANDACIDE ORAL SUSPENSION. Your child may need urgent medical attention or hospitalisation

Tell your doctor if you notice any of the following:

Frequent side effects

- Gastrointestinal disturbances including nausea , vomiting and diarrhoea

Frequency unknown side effects:

- Swelling, of the area beneath the skin or mucosa including swelling of the face
- Hypersensitivity
- Rash including urticarial (a rash of round, red welts on the skin that itch intensely,)

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- Stevens-Johnson syndrome (is a rare, serious disorder of the skin and mucous membrane

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via

the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s

publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CANDACIDE ORAL SUSPENSION.

5. How to store CANDACIDE ORAL SUSPENSION

- Store all medicines out of reach of children
- Store at or below 25 °C.
- Do not freeze
- Store your medicine in the original packaging in order to protect from light.
- Do not use this medicine after the expiry date shown on the packaging.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What CANDACIDE ORAL SUSPENSION contains

The active substance is Nystatin.

Preservatives

Methyl hydroxybenzoate 0,18 % *m/v*

Propyl hydroxybenzoate 0,02 % *m/v*

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Sodium benzoate 0,2 % *m/v*

The other ingredients are:

Citric acid monohydrate, flavour cherry S-2418,
flavour peppermint C-7531, glycerol, methyl hydroxybenzoate, polysorbate-80, propyl
hydroxybenzoate, simethicone, sodium benzoate, sodium citrate, sodium saccharin, sorbitol
solution (70 %) (noncrystallising), xanthan gum.

WHAT CANDACIDE ORAL SUSPENSION LOOKS LIKE AND CONTENTS OF THE PACK

A creamish yellow, opaque suspension

20 ml; 30 ml and 50 ml suspension in amber glass bottles with screw on cap. Dropper included.

Holder Of Certificate Of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd
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Stormill, Ext. 1,
Roodepoort,
1724

This Leaflet Was Last Revised In

24 January 2022

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8. REGISTRATION NUMBER(S)

31/20.1.7/0288

S2 BOT 0400717 (Botswana) (20 ml)

NS1 04/20.1.7/1001 (Namibia) (20 ml)