SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

CANDACIDE ORAL SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CANDACIDE ORAL SUSPENSION

Each 1 ml contains:

Nystatin	100 000 units

Preservatives

Methyl Parahydroxybenzoate	0,18 % *m/v*
Propyl Parahydroxybenzoate	0,02 % *m/v*
Sodium benzoate	0,2 % *m/v*

Contains sugar:

Liquid sorbitol: 500 mg/ml

Glycerol: 100 mg/ml

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

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension

Creamish yellow, opaquely, viscous suspension with a characteristic odour and sweet taste with a slight bitter

after-taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

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

4.2 Posology and Method of Administration

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.

(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 a 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

Method of Administration

SHAKE THE BOTTLE BEFORE USE.

4.3 Contraindications:

- Hypersensitivity to nystatin or any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Candacide Oral Suspension should not be used for the treatment of systemic mycoses.

If irritation or sensitization develops, treatment should be discontinued.

CANDACIDE ORAL SUSPENSION contains propyl p-hydroxybenzoate and methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed).

Sorbitol:

CANDACIDE ORAL SUSPENSION contains liquid sorbitol non crystallising. Patients with hereditary fructose intolerance (HFI) should not take/be given **CANDACIDE ORAL SUSPENSION**

Glycerol:

CANDACIDE ORAL SUSPENSION contains glycerol which may cause headache,stomach upsets and diarrhoea

4.5 Interaction with other medicines and other forms of Interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal reproductive studies have not been conducted with nystatin.

It is not known whether nystatin can cause foetal harm when administered to a pregnant woman or can affect

reproductive capacity; however absorption of nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved.

Lactation

It is not known whether Nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when Nystatin is prescribed for a breast-feeding woman.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not relevant

4.8 Undesirable effects

MedDRA System Organ Class	**Frequent**	**Less Frequent**	**Frequency Unknown**
Immune system disorders			hpersensitivity -Angioedema including facial oedema
Gastrointestinal disorders	Gastrointestinal disturbances -nausea -vomiting -diarrhoea		
***Skin and subcutaneous tissue* disorders**			-Rash including - Urticaria -Steven Johnson syndrome

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction"**

Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/

4.9 Overdose

Treatment is symptomatic and supportive

Since the absorption of nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity. Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Category and class: A 20.1.7 (Antifungal antibiotic)

ATC code: D01AA01

Nystatin is a mixture of antifungal polyenes produced by the growth of certain strains of *Streptomyces noursei*, or by any other means. It consists largely of Nystatin A_1.

CANDACIDE ORAL SUSPENSION is an antibiotic with antifungal activity against a wide variety of yeasts and yeast like fungi especially the Candida genus. The antifungal activity of **CANDACIDE ORAL SUSPENSION** is at least in part depending on its binding to a sterol moiety, primarily ergosterol, present in the membrane of sensitive fungi, which results in an increase in the permeability of the membrane and leakage of intra-cellular components.

Candacide Oral Suspension exhibits no appreciable activity against bacteria, protozoa or viruses

5.2 Pharmacokinetic properties:

Absorption

Gastro-intestinal absorption of CANDACIDE ORAL SUSPENSION is insignificant.

Nystatin is a tetraene macrolide. There is no data available on the pharmacokinetics as it is not absorbed from the gastro-intestinal tract, skin or vagina and most of the use is topical. Microbial growth-inhibiting concentrations have been shown to be in the range 3-6 mg/l.

Elimination

Most orally administered **CANDACIDE ORAL SUSPENSION** is passed unchanged in the stool

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Preservatives

- Methyl hydroxybenzoate 0,18 % *m/v*
- Propyl hydroxybenzoate 0,02 % *m/v*
- Sodium benzoate 0,2 % *m/v*

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 %) non crystallising
- Xanthan gum

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 ^{0}C.

Do not freeze.

Protect from light

Keep container tightly closed.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

Shake well before use.

Dilution is not recommended as this may reduce therapeutic efficacy.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill Ext. 1

Roodepoort

1724

South Africa

8. REGISTRATION NUMBER(S)

31/20.1.7/0288

S2	BOT 0400717 (Botswana) (20 ml)
NS1	04/20.1.7/1001 (Namibia) (20 ml)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08 March 2001

10.DATE OF REVISON OF THE TEXT

24 January 2022