NEW ZEALAND DATA SHEET

1. FUNGILIN (Amphotericin B) 10mg lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fungilin (amphotericin B lozenge) contains 10mg of amphotericin.

Fungilin (Amphotericin B lozenges) is an antifungal polyene macrolide antibiotic obtained from Streptomyces nodosus.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge: 10mg; round, pale, yellow.

4. CLINICAL PARTICULARS

4.1 Therapeutical indications

Lozenge:
For the treatment of candidal lesions (thrush) of the oral and perioral areas.

4.2 Dose and method of administration

Adult Dosage:

Lozenges:

Dissolve 1 slowly in the mouth four times a day. Depending on the severity of infection, the dose may be increased to 8 lozenges daily.

To clear the condition fully may require 10-15 days' treatment.

Administration of Fungilin for oral and intestinal candidosis should be continued for 48 hours after clinical cure to prevent relapse.

The lozenges should be taken after meals and at bedtime. Patients wearing dentures should be especially careful to cleanse them thoroughly and to remove them while sucking the lozenge to allow the active material to reach all tissues.

Elderly:

No specific dosage recommendations or precautions.

4.3 Contraindications

FUNGILIN is contraindicated in patients with a history of hypersensitivity to amphotericin B or any other component of the FUNGILIN formulation. Orally administered amphotericin B is not to be used for the treatment of systemic fungal infections.

4.4 Special warnings and precautions for use

No data available.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Fertility:

No data available

Pregnancy:

Category B3

There are no adequate and well-controlled studies in pregnant women. Oral forms of amphotericin B should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation:

It is not known whether amphotericin B is excreted in human milk. Though gastrointestinal absorption is insignificant, caution should be exercised when amphotericin B is prescribed for a nursing woman

4.7 Effects on ability to drive and use machines

No data has been established on the effect that amphotericin B has on the ability to drive & use machines, therefore it can only be assumed that it is safe or unlikely to produce an effect.

4.8 Undesirable effects

Since amphotericin B is not appreciably absorbed when taken orally, even at high doses, adverse effects following oral administration of up to 3 g daily have been uncommon. Rash, glossitis, and gastrointestinal distress, including nausea, vomiting, and diarrhea have been reported occasionally. Urticaria, angioedema, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported rarely; an association between these events and administration of FUNGILIN is unclear. Skin exfoliation has been reported during post marketing surveillance. Transient yellowing of the teeth may occur with the use of the lozenge formulations, which can easily be removed by brushing.

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 https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

There is little information available regarding overdose with oral dosage forms of amphotericin B. Since absorption of amphotericin B from the gastrointestinal tract is negligible, even in high doses, overdose should not normally result in systemic toxicity. In case of overdose, usual measures to remove drug substance from the gastrointestinal tract should be considered.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This medicine is active against a wide range of yeasts and yeast-like including Candida albicans. Candida albicans is generally quite susceptible to

the medicine, but other Canidida species may be less susceptible. While amphotericin B has demonstrated antifungal activity toward many fungal species, oral forms of amphotericin B are indicated for oral & intestinal candidasis (see section 4.1, Therapeutic indications) FUNGILIN is without effect on bacteria, rickettsiae & viruses.

Fungal species with decreased susceptibility to amphotericin B have been isolated after serial passage in culture media containing the drug, and from some patients receiving prolonged therapy.
Some resistant strains of Candida have been isolated from immunocompromised patients receiving prolonged treatment with amphotericin B.

However, strains of Candida albicans resistant to both amphotericin B and fluconazole have emerged in a few patients who have received repeated or prolonged courses of fluconazole.

Reports of amphotericin B resistant fungi are infrequent.

5.2 Pharmacokinetic properties

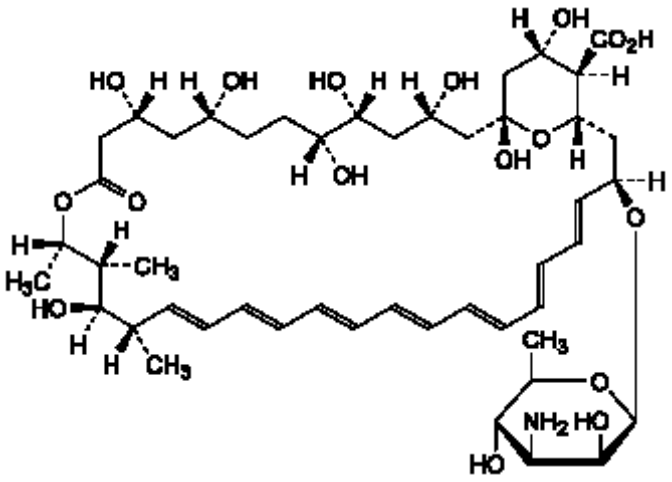
Absorption from the gastrointestinal tract is negligible even with very large doses. Extensive clinical experience has not shown problems of toxicity of sensitisation.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

Chemical structure:



$C_{47}H_{73}NO_{17}M$,
Molecular weight: 924

6.1 List of excipients

Mannitol, acacia, stearic acid, sodium cyclamate, saccharin sodium, polyvinyl alcohol, purified talc, orange flavour (051226T), orange flavour (17410033) and Curacao flavour.

6.2 Incompatibilities
No data available.

6.3 Shelf life
18 months from date of manufacture.

6.4 Special precautions for storage
Lozenges:
Store below 25°C.

6.5 Nature and contents of container
Glass, amber, bottle, containing 20 lozenges.

6.6 Special precautions for disposal (and other handling)
No data available.

7. MEDICINE SCHEDULE
Prescription medicine.

8. SPONSOR
Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

9. DATE OF FIRST APPROVAL
9th July 2008

10. DATE OF REVISION OF THE TEXT
May 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All sections revised	Update to the SPC-style format