

# New Zealand Data Sheet

## Fungilin

*Amphotericin B*

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### Presentation

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*Lozenge*: 10mg; round, pale, yellow engraved Squibb.

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### Uses

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#### *Actions*

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

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 *Candida* 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 candidiasis (see **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.

#### *Pharmacokinetics*

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

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## Indications

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### ***Lozenge:***

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

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## Dosage And Administration

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### ***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.

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## Contraindications

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FUNGILIN is contra-indicated 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.

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## Warnings And Precautions

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### ***Pregnancy/Children:***

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.

### ***Nursing Mothers***

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

### ***Effect on ability to drive & 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.

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## **Adverse Effects**

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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.

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## **Overdosage**

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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.

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## **Pharmaceutical Precautions**

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Shelf Life:

18 months from date of manufacture

***Storage:***

## Lozenges:

Store below 25°C.

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## Medicine Classification

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Prescription Medicine

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## Package Quantities

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### Lozenge:

10mg, 20s.

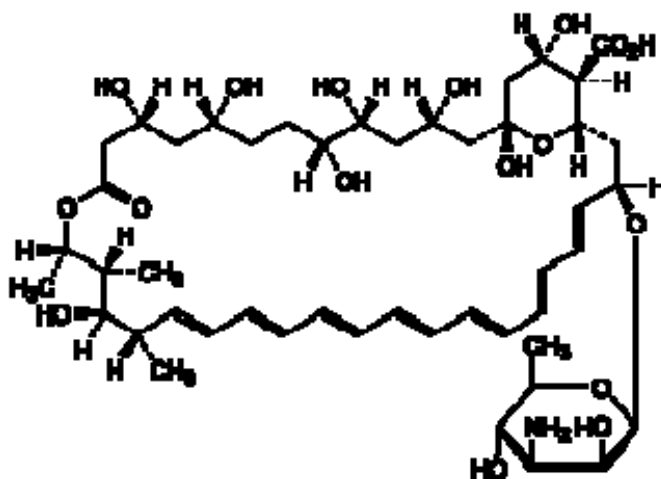
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## Further Information

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Fungilin (amphotericin B lozenge) contains 10mg of amphotericin, mannitol, acacia, stearic acid, sodium cyclamate, saccharin sodium, polyvinyl alcohol, talc, flavour blood orange, flavour natural orange & flavour curacao.

Chemical Structure



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

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## Name And Address

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Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics  
58 Richard Pearse Drive  
Airport Oaks

Mangere  
AUCKLAND

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## **Date of Preparation**

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13 February 2010