Fungilin

*Amphotericin B*

**Presentation**

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

**Uses**

**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 candidasis (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 of sensitisation.
Indications

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

Dosage And 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.

Contraindications

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.

Warnings And Precautions

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.

**Adverse 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.

**Overdosage**

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.

**Pharmaceutical Precautions**

**Shelf Life:**

18 months from date of manufacture

**Storage:**
Lozenges:

Store below 25°C.

Medicine Classification

Prescription Medicine

Package Quantities

Lozenge:

10mg, 20s.

Further Information

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

\[ \text{C}_{47}\text{H}_{73}\text{NO}_{17} \quad \text{M} \quad 924 \]

Name And Address

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