

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	MYCOREN TABLETS (Nystatin Tablets 500,000 I.U)
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Pack Insert:

MYCOREN ORAL TABLETS (NYSTATIN)

Pharmaceutical information:

Each tablet contains

Nystatin BP 500000 I.U

Introduction:

Mycoren is a brand of Nystatin B.P a polyene antifungal antibiotic obtained from *Streptomyces noursei*.

Microbiological action:

Mycoren is both fungicidal and fungistatic *in vitro* against a wide variety of yeast and other fungi like yeast. It is effective against a variety of both pathogenic and non pathogenic species of candida, especially candida albicans. It, however, exhibits no activity against protozoa, bacterial, trichomands and viruses.

Mechanism of action:

It acts by binding the sterols in the cell members of susceptible fungi which results in a change of the permeability of the cell membrane, allowing thereby, leakage of intracellular components.

Indications:

Mycoren is indicated for the treatment of mucocutaneous mycotic infections (Candidiasis) of the mouth and the alimentary tract, caused by *Candida* (*Monilia*) *albicans* and other species candida.

Contraindications: Hypersensitivity to Nystatin.

Precaution:

Should a hypersensitivity reaction occur, administration of the drug should be immediately withdrawn and appropriate measures taken.

Adverse effect:

Mycoren being virtually non-toxic and sensitizing, is well tolerated by all age groups including debilitated infants, even on prolonged administration.

Pharmacokinetics:

Mycoren is not absorbed from intact skin. When taken orally, Gastrointestinal absorption is insignificant.

No detectable blood levels are seen when administered in the recommended doses. Most of the drug is passed unchanged in the stools.

Dosage:

The recommended dose of mycoren should be taken 4 to 5 times daily, for as long as 14 days, if necessary. The dosage regimen should be continued for at least 48 hours after the complete disappearance of symptoms. To treat the infected mucosa in the esophagus or the posterior pharynx.

Usual dosage - 500,000 to 1 million units (1 to 2 tablets or capsules) three times daily. Treatment should generally be continued for at least 48 hours after clinical cure to prevent a relapse.

Storage:

Mycoren Oral Tablets should be stored in cool dry place, protected from light. Keep out of reach of children.

Presentation:

Blister pack of 10x10's Tablets

MANUFACTURED BY:-



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