MEDISTAN ®

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about MEDISTAN
Each MEDISTAN capsule for oral administration contains 500000 IU nystatin with the following excipients: magnesium stearate, croscarmellose sodium, and lactose monohydrate.
Each 5 mL of MEDISTAN oral suspension contains 500000 IU nystatin. MEDISTAN suspension is a ready-to-use suspension with the following excipients: sucrose, sodium saccharine, sodium carboxymethylcellulose, methylparaben, propylparaben, banana flavor, menthol, and purified water.
Nystatin is a polyene antifungal active against a wide variety of yeasts and yeast-like fungi including Candida albicans and other Candida species. Nystatin exerts its antifungal activity by binding to sterols and altering the fungal cell membrane.
- MEDISTAN taken orally is used for the prophylaxis and treatment of oral candidiasis (thrush, perlèche, glossitis, stomatitis and gingivitis), esophageal and intestinal candidiasis.
MEDISTAN is compatible with all commonly employed antibiotics. MEDISTAN is often prescribed during antimicrobial, corticosteroid, chemotherapy or immunosuppressive therapy to prevent possible candidiasis.
- MEDISTAN may also be used as an adjunctive therapy to reduce intestinal candidal colonization in patients with coexisting intestinal candidiasis and vulvovaginal candidiasis or intestinal candidiasis and cutaneous candidiasis.
MEDISTAN administered orally as a suspension is used in conjunction with a topical antifungal for the treatment of candidal diaper dermatitis in patients with coexisting intestinal candidiasis.
The way to take MEDISTAN
Take MEDISTAN as directed by your physician. Do not discontinue the treatment without consulting your doctor. Dosage and duration of treatment are individualized on the basis of the condition under treatment.
The usual recommended dosage is:

Indications	**Dosage**		
	Adults (more than 15 years)	**Children** (30 months-15 years)	**Infants** (less than 30 months)
Treatment of intestinal or esophageal candidiasis	8 to 12 capsules per day (4 to 6 million IU per day) divided in 3 or 4 doses Doses of 1 to 2 capsules or 5 mL to 10 mL of the suspension (500000 or 1 million	2 to 8 capsules per day or 10 mL to 40 mL of the oral suspension per day administered in 3 or 4 doses (1 to 4 million IU per day)	5 mL to 30 mL of the oral suspension per day administered in 3 or 4 doses (500000 IU to 3 million IU per day)

	IU) 3 or 4 times daily may also be used		
Treatment of oral candidiasis (lesions of the mouth)	4 mL (400000 IU) to 6 mL (600000 IU) 4 times per day Higher doses may be needed in immunocompromised patients	4 mL (400000 IU) to 6 mL (600000 IU) 4 times per day	2 mL (200000 IU) (1 mL in each side of mouth) 4 times per day
Prophylaxis of intestinal candidiasis in patients receiving antibacterials	2 capsules or 10 mL of the suspension (1 million IU) per day	1 mL (100000 IU) 4 times daily	1 mL (100000 IU) 4 times daily
Prophylaxis of oral candidiasis in neonates	-	-	1 mL (100000 IU) once daily
Adjunctive therapy for the treatment of candidal diaper rash	-	-	1 mL (100000 IU) 4 times daily
Treatment of coexisting intestinal candidiasis in women with vulvovaginal candidiasis	1 to 2 capsules (500000 IU to 1 million IU) 3 times daily	-	-

For the treatment of oral candidiasis, place one half of the dose in each side of the mouth, rinse with the suspension so it is spread uniformly, retaining the drug as long as possible before swallowing. Do not swallow any other liquid or food for as long as possible.
Shake well before each use of the suspension.

Duration of treatment

There should be no interruption or discontinuation of medication until the prescribed course of treatment is completed even though symptomatic relief may occur within a few days. Continue use at least 2 days after symptoms have subsided. Treatment may last for 2 to 3 weeks.
When given concomitantly with an oral antibacterial agent, the suspension should be continued at least as long as the antibacterial agent.

In case of overdose

There have been no reports of serious toxic effects or superinfections after ingestion of excessive doses. In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention, general measures may be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in case of known hypersensitivity to any of the components.

Precautions

- This drug is not to be used for the treatment of systemic mycoses.
- Notify your doctor if symptoms of local irritation develop.
- Pregnancy: Systemic absorption of nystatin is negligible; however, this drug should be given to a pregnant woman only if clearly needed.
- Lactation: It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is administered to a nursing mother.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently. No incompatibilities with other medications have been described. Avoid concomitant use of drugs that may affect the intestinal transit or that may form a barrier to the contact of the drug with the intestinal mucosa; these may affect the efficacy of the drug.

Adverse reactions

This drug is generally well tolerated by all age groups, even with prolonged therapy. In rare cases it may produce gastrointestinal distress, nausea, vomiting or diarrhea, which resolves on discontinuation of treatment. Allergic reactions have been rarely reported.
Inform your doctor if any adverse effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.
After opening, the oral suspension must be used within 7 days.

Pack Presentation

MEDISTAN capsules, 500000 IU, pack of 20 capsules
MEDISTAN oral suspension, 500000 IU/5 mL, bottle of 60 mL with a dosing cup

Revision date: 02/2022

MEDC5/009
Manufactured by Mediphar Laboratories -Lebanon