Rx For the use of a licensed physician or hospital or laboratory only

Amphotericin B Oral Suspension

PHORICIN-O

100mg/ml

For use in the Oral Cavity or for Gastrointestinal use

COMPOSITION

Each ml of suspension contains:
Amphotericin B BP……100mg
In a flavoured base…….q.s.
Approved colour added.

1. WHAT IS AMPHOTERICIN B ORAL SUSPENSION AND WHAT IS IT USED FOR?

Amphotericin B Oral Suspension contains the active substance amphotericin B, for the treatment of fungal infections (antifungal antibiotic).
Amphotericin B Oral suspension is suitable for the treatment of: oral thrush and for the prevention of yeast overgrowth in the gastrointestinal tract in immunocompromised patients. Particularly suitable for infants, toddlers and patients with reduced difficulty.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AMPHOTERICIN B ORAL SUSPENSION?

Amphotericin B Oral Suspension must not be used if you are allergic to amphotericin B, parabens, sodium metabisulphite, cinnamon (cinnamaldehyde), benzyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, linalool or any of the other ingredients of this medicine. This also applies if you are hypersensitive to Peru balm (cross-allergy).
– for the treatment of systemic fungal infections (affecting internal organs).

Warnings and Precautions

Talk to your doctor or pharmacist before using Amphotericin B Oral Suspension.
Children: Due to the high osmolarity of Amphotericin B Oral suspension (approx. 1700 mOsmol/l), its use in premature babies is not recommended.
Elderly people: Results from clinical trials with Amphotericin B Oral suspension did not indicate that special precautions are needed in elderly patients.
Note: Discoloration may occur upon contact with garments.
Other medicines and Amphotericin B Oral Suspension Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and Breast-feeding

If you are pregnant or breastfeeding, or if you suspect you may be pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.
There are insufficient data for the use of Amphotericin B Oral suspension in pregnant women. Amphotericin B, the active ingredient from Amphotericin B Oral suspension, has been insufficiently tested in animal experiments with regard to possible harmful effects on prenatal development. Although the absorption of amphotericin B from the gastrointestinal tract into the body is low, Amphotericin B Oral suspension in pregnancy should only be used on explicit.
Use your doctor's instructions, and only if they have previously weighed the benefits of the treatment against possible risks to the unborn child. It is not known whether the active ingredient from Amphotericin B Oral suspension is excreted in breast milk. Although the absorption of the active substance from the gastrointestinal tract into the body is low, you should only use Amphotericin B Oral Suspension during breastfeeding as instructed by your attending physician, and only after the latter has carried out a corresponding benefit/risk assessment.

Ability to drive and use machines

No special precautions are required.

Amphotericin B Oral suspension contains sodium benzoate

This medicine contains 2 mg sodium benzoate per 1 ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks of age).
Sodium benzoate can cause local irritation.

Amphotericin B Oral suspension contains ethanol (alcohol)

Amphotericin B Oral suspension contains 0.51 vol.-% alcohol. Amphotericin B Oral suspension contains sodium compounds This medicine contains less than 1 mmol (23 mg) of sodium per 1 ml, i.e. it is almost "sodium-free".

Amphotericin B Oral Suspension contains flavors with benzyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool.

Citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool can cause allergic reactions.

3.HOW TO USE AMPHOTERICIN B ORAL SUSPENSION?

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Method of use for use in the oral cavity or for gastrointestinal use. Unless otherwise prescribed by the doctor, the usual dosage is:
Oral thrush: For all ages (except premature babies), it is recommended to drip 1 ml of suspension with the attached pipette into the mouth 4x daily after meals or before going to bed and to distribute it in the mouth for at least 1 minute, so that a good wetting of the entire oral cavity is achieved. The suspension can then be swallowed.
To do this, please shake the bottle vigorously before use. Then use the pipette to draw the suspension to the marking stroke. In infants and young children, it has proven useful to additionally brush the affected areas with a cotton swab on which some Amphotericin B Oral suspension has been applied beforehand.
Prevention of yeast overgrowth in the gastrointestinal tract:
Outpatients: 1 ml suspension 4 times a day Intensive care patients:
up to 20 ml suspension/day as a single dose
In seriously ill patients with difficulty swallowing, Amphotericin B Oral suspension can be administered via a gastric tube.

Dosage for impaired renal function:

Due to the negligible intake from the gastrointestinal tract into the body, there are no special dosage recommendations.
In the case of oral thrush, the treatment should last 2–3 days after the disappearance of the visible symptoms (adults: white to brownish coverings of the oral mucosa that are difficult to remove, sometimes thick closed membranes reaching into the pharynx or throat; dry mouth, burning pain; Infants: whitish, small-spotted deposits).
Prevention of yeast overgrowth in the gastrointestinal tract should be carried out during the period of treatment with broad-spectrum antibiotics (agents for infectious diseases), corticoids or cytostatic (agents e.g. for cancer treatment) to prevent the growth of yeasts in the intestine.
Talk to your doctor or pharmacist if you have the impression that the effect of Amphotericin B Oral Suspension is too strong or too weak.

If you use more Amphotericin B Oral Suspension than you should, very little information is available on how to overdose when using Amphotericin B orally.

Since the absorption from the gastrointestinal tract into the body after oral administration, even at high doses, is negligible, side effects of amphotericin B on the organism are not to be expected even with overdose. If necessary, the usual measures for the removal of drugs from the gastrointestinal tract should be taken.
If you forget to use Amphotericin B Oral Suspension , do not apply a double dose if you forget to use it before. Continue the treatment as indicated.
If you stop using Amphotericin B Oral Suspension, your condition may worsen. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4 .WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, this medicine can cause side effects, although not everyone gets them. When evaluating side effects, the following frequency information is usually used:

Very common	may affect more than 1 in 10 people
Frequently	may affect up to 1 in 10 people
Occasionally	may affect up to 1 in 100 people
Seldom	may affect up to 1 in 1000 people
Very rare	may affect up to 1 in 10000 people
Not known	Frequency based on available Data cannot be estimated

Possible side effects

If you are affected by any of the following side effects, do not continue to use Amphotericin B Oral Suspension and consult your doctor as soon as possible.
Diseases of the gastrointestinal tract: Inflammation of the mucous membrane of the tongue (glossitis) or gastrointestinal complaints such as nausea, vomiting or diarrhea can often occur. An orange dental plaque that comes from the color of the suspension can be easily removed by brushing your teeth.
Diseases of the skin and subcutaneous cell tissue: Rashes can often occur. In occasional cases, sometimes severe hypersensitivity reactions have been reported.
Other possible side effects: Cinnamon (cinnamaldehyde) can cause skin irritation. Benzyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool can cause allergic reactions. Due to the content of parabens (alkyl-4-hydroxybenzoates), hypersensitivity reactions can occur, even with a time delay.
Sodium meta bisulphite can rarely cause severe hypersensitivity reactions and airway cramping (bronchospasm). Reporting side effects If you get any side effects, talk to your doctor or pharmacist.

5.HOW TO STORE AMPHOTERICIN B ORAL SUSPENSION

Keep this medicine out of the reach of children.
Do not use this medicine after the expiry date which is stated on the container and carton after EXP. The expiration date refers to the last day of the specified month.
Do not store above 30°C.
Keep the bottle well closed! Never dispose of medicines via the waste water (e.g. not via the toilet or sink). Ask your pharmacy how to dispose of the medicine if you stop using it. They thus contribute to the protection of the environment.

6. CONTENTS OF THE PACKAGE AND FURTHER INFORMATION

What Amphotericin B Oral Suspension contains

The active substance is Amphotericin B. 1 ml of suspension contains 100 mg of amphotericin B (equivalent to 100,000 IU) in an aqueous solution. The other ingredients are: methyl-4-hydroxybenzoate (Ph.Eur.) and propyl-4-hydroxybenzoate (Ph.Eur.) (Parabens: E216, E218), sodium benzoate (E211), sodium metabisulphite (E223), sodium monohydrogen phosphate dodecahydrate (Ph.Eur.), sodium dihydrogen phosphate dihydrate, potassium chloride, saccharin sodium 2 H2 O, glycerol (85% v/v), citric acid anhydrous, carmellose sodium, erythrosin (E127), ethanol (96% v/v), cinnamaldehyde, flavourings (contain triethyl citrate, all-rac-α-tocopherol, triacetin) and purified water (Ph.Eur.). Contains flavors with benzyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool. The supplied pipette holds 1 ml of suspension.

What Amphotericin B Oral Suspension looks like and contents of the pack

Amphotericin B Oral Suspension is an orange suspension and available in bottles of 50 ml, each with a pipette for instillation into the mouth.

Manufactured By:
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WARDHA - 442 006

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