

OSPAMOX FILM-COATED TABLET/ ORAL SUSPENSION

Consumer Medication Information Leaflet (RiMUP)

Amoxicillin Trihydrate (500mg, 1000mg, 125mg/5ml, 250mg/5ml)

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What Is Ospamox Used For

Ospamox is used to treat infections caused by bacteria in different parts of the body such as:

- Infections of the ear, throat, nose and sinuses
- Chest infections such as bronchitis and pneumonia
- Infections affecting urinary and genital tract
- Prevention of heart infections during mouth or throat surgery
- Stomach ulcers caused by the bacterium *Helicobacter pylori*. Ospamox works by killing the bacteria that cause these infections. Ospamox can also be used to prevent infection.

Your doctor may have prescribed Ospamox for another reason.

How Ospamox Works

Ospamox is an antibiotic. It belongs to a group of antibiotics called penicillins which is amoxicillin. It is used to treat infections caused by bacteria which are sensitive to amoxicillin.

Before You Use Ospamox

- When you must not use it

- If you are allergic (hypersensitive) to amoxicillin, penicillins, cephalosporins or to any of the other ingredients of this medicine
- If you have glandular fever or a cancer of the bone marrow
- Severe stomach infections with persistent diarrhea and vomiting
- If you have bronchial asthma and hay fever

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. As a precautionary measure, amoxicillin should only be used during pregnancy if in the judgement of the physician the potential benefits outweigh the possible hazards.

Breast-feeding

This medicine passes into breast milk in small quantities, therefore in some cases it may be necessary to stop breastfeeding.

- Before you start use it

Talk to your doctor or pharmacist before taking Ospamox if you have:

- any allergic conditions
- liver disease
- severe and persistent diarrhea
- an inherited disorder that increases the levels of a substance called phenylalanine as the syrup preparations contain Aspartame

- Taking other medicines

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines. Some medicines can cause problems if you take them with Ospamox.

Take care with the following medicines:

- Allopurinol (used to treat gout): you may have a higher risk of skin reactions.
- Bacteriostatic antibiotics such as tetracyclines and chloramphenicol: combination causes Ospamox to lose efficacy.
- Probenecid: reduces the kidney elimination of Ospamox resulting in higher blood concentration of Ospamox.
- Contraceptive pills: there is a risk of contraceptive pills not working to their greatest effect.
- Antacid: reduces Ospamox absorption

Taking with food

You can take Ospamox either before, during or after meals.

How To Use Ospamox

- How much to use

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is 1,500 mg to 2,000 mg daily in two to three divided doses.

The recommended dose for children is 30 - 60 mg/kg/day in two to three divided doses.

People with kidney disease

Your doctor may have to lower the dose.

- How to use it

Ospamox 500mg & 1000mg film coated tablet

Swallow your tablets whole with a drink of water. Do not crush or chew the tablets.

Ospamox 125mg/5ml & 250mg/5ml granules for oral suspension

To reconstitute the suspension fill the bottle with fresh tap water approximately 1 cm below the filling mark, close and shake well at once. After the foam has settled, slowly add fresh tap water exactly to the filling mark. Shake vigorously again. The white to slightly yellowish suspension is now ready for use. Shake the bottle well before every withdrawal.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

Always keep taking this medicine until the course is finished, even if you feel better. If you stop taking this medicine too soon, the infection may come back. Also, the bacteria may become resistant to the medicine. If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

It is important to use your medicine every day. However, if you forget to use one or more doses, take OSPAMOX as soon as you remember and then go on as prescribed.

- If you use too much (overdose)

If you take too much of this medicine (overdose), talk to your doctor or go to a hospital straight away, and show them the pack. The most likely signs of overdose are nausea, vomiting, diarrhea, abdominal pain.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While You Are Using It

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking OSPAMOX. Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give OSPAMOX to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines
This medicine has no known influence on the ability to drive and use machines.

Side Effects

Like all medicines, OSPAMOX can cause side effects, although not everyone gets them.

If you notice any of the following serious side effects, talk to your doctor immediately or go to a hospital straight away.

Nausea and diarrhea are occasional temporary side effects that may occur.

Rarely, allergic reactions like rashes, fever, joint pain, severe or itchy skin,

swelling of the lower layer of skin and blood disorder problems [e.g. low levels of platelets (thrombocytopenia), severe lowered white blood cell count (agranulocytosis), decrease in white blood cell (leukopenia), increase in certain white blood cells (eosinophilia)] have occurred.

Like other antibiotics, amoxicillin may cause headache, tiredness, inflammation of tongue, inflammation of mouths and lips, fever, joint pain, swelling of the lower layer of skin and inflammation of the spaces between renal tubules.

Individuals with inflammation of brain membranes (meningitis) may run an increased risk of developing fits.

Transient increases in liver enzymes are also seen.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Ospamox

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Ospamox 500mg & 1000mg film coated tablet

Store below 25°C, protect from light and moisture.

Ospamox 125mg/5ml & 250mg/5ml granules for oral suspension

After reconstitution: Store in the refrigerator (2°C - 8°C), the suspension is usable for 14 days. Store the granules below 25°C, protect from light and moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Ospamox 500mg film coated tablet

The film-coated tablets are white to cream-coloured, oblong, biconvex, scored on both sides.

Ospamox 1000mg film coated tablet

The film coated tablets are white to cream-coloured, oval, biconvex, scored on both sides.

Ospamox 125mg/5ml: White to slightly yellowish powder.

The powder for oral suspension is packed in an amber glass bottles 60 ml with screw closure (press + turn) and sealing membrane.

Ready-for-use suspension: White to yellowish suspension.

Ospamox 250mg/5ml: White to slightly yellowish powder.

The powder for oral suspension is packed in an amber glass bottles 100 ml with screw closure (press + turn) and sealing membrane.

Ready-for-use suspension: White to yellowish suspension.

Ingredients

Active substance

The active substance is amoxicillin (as trihydrate).

Inactive ingredients

Ospamox 500mg & 1000mg film coated tablet

Core: magnesium stearate, polyvidone, sodium starch glycolate, cellulose microcrystalline
Coating: titanium dioxide, talc, hypromellose.

Ospamox 125mg/5ml & 250mg/5ml granules for oral suspension

Citric acid anhydrous, Sodium Benzoate, Aspartame, Talc, Trisodium citrate, anhydrous, Guar, Silicon dioxide, precipitated, Lemon flavouring, Peach-apricot flavouring, Orange flavouring.

MAL Number

Ospamox 500mg film coated tablet

- MAL19890612AZ

Ospamox 1000mg film coated tablet

- MAL19890613AZ

Ospamox 125mg/5ml -

MAL19890608AZ

Ospamox 250mg/5ml-

MAL19890609AZ

**Manufacturer and Product
Registration Holder**

Manufacturer

Sandoz GmbH Biochemiestrasse 10

6250 Kundl

Austria

Product Registration Holder

Novartis Corporation (Malaysia)

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Malaysia

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