

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ospamox DT

500 mg, tablets for oral suspension; 750 mg, tablets for oral suspension, 1000 mg, tablets for oral suspension

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Ospamox DT is and what it is used for
2. Before you take Ospamox DT
3. How to take Ospamox DT
4. Possible side effects
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1. WHAT OSPAMOX DT IS AND WHAT IT IS USED FOR

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

Ospamox DT is used for the treatment of:

- Infections of the ear, nose, throat or sinuses
- An infection of the chest, such as inflammation of the lungs (pneumonia) and respiratory tract (bronchitis)
- Infections of the bladder
- Prevention of heart infections (endocarditis) during the operation of the mouth and throat
- Treatment of stomach ulcer caused by *Helicobacter pylori*
- Early stages of Lyme disease (caused by a tick bite).

2. BEFORE TAKING OSPAMOX DT

Do not take Ospamox DT:

- If you are hypersensitive (allergic) to amoxicillin, Penicillins, cephalosporins or any ingredient of Ospamox-DT (see section 6, "other information").

Pay special attention to:

Before taking Ospamox-DT, tell your doctor if you have or have ever had:

- Renal Disease: your doctor may adjust a dose
- Infectious Mononucleosis (a viral infection) or leukemia (malignant blood disease): there is a greater risk of cutaneous reactions
- Epilepsy (seizures with cramps): there is a higher risk of attack
- Urinary catheter: it is necessary to drink a large amount of liquid, to prevent the formation of crystals.

This medicine may also alter the results of the urine or blood sugar tests. If you have diabetes (diabetes mellitus) or perform routine urine or blood test, tell your doctor, because other tests can be performed.

Taking other medicines

Please tell your doctor or pharmacist if you are using or have used any other medicine. This includes medicines that can be purchased without a prescription. Some medicines can cause problems if you are taking them at the same time as Ospamox DT.

Pay attention when taking the following medicines:

- Allopurinol (used to treat gout): there is a greater risk of cutaneous reactions.
- Methotrexate (used to treat inflammation of the joints [arthritis]): may increase the toxicity of methotrexate
- Digoxin (used to treat certain diseases of the heart): absorption of Digoxin may be increased
- Anticoagulants (medications to prevent blood clotting), such as coumarin: can cause prolonged bleeding time.
- Birth control pills (tablets that are used for the prevention of pregnancy): can reduce the effect of the contraceptive pills.

Taking Ospamox-DT with food and drink

Ospamox DT can be taken before, during or after a meal.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

Data on a limited number of pregnant women exposed to the action of amoxicillin indicate that there are no detrimental effects of amoxicillin on pregnancy or on the health of the fetus or newborn. As a precautionary measure, amoxicillin during pregnancy can be used only if the doctor believes that the potential benefits outweigh the possible risks.

This medicine passes into breast milk in small amounts, so it is in some cases necessary to discontinue breast-feeding.

Driving and using machines

There are no data suggesting that the medicine affects the ability to drive and use machines.

Important information about some of the integral components of Ospamox-DT

Ospamox DT tablets contain the sweetener aspartame, which is a source of phenylalanine, which can be detrimental for patients with phenylketonuria (an inherited disease that is characterized by abnormal protein metabolism).

3. HOW TO TAKE OSPAMOX DT

Always take your medicine exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

The tablets can be administered in two ways. Tablets can be dissolved in water and swallowed, or swallowed with a glass of water. The tablets can be broken in order to more make swallowing easier.

The usual dose for adults and children older than 12 years is from 750 mg to 3000 mg per day divided into 2-3 doses.

For the prevention of heart infections:

Adults: 2000-3000 mg administered one hour before any surgical procedure.

Your doctor will decide how long you will take Ospamox DT.

Patients with renal impairment

The lower dose of the medicine is used in patients with renal impairment.

If you have taken more Ospamox-DT, than you should

If you have taken a higher dose of Ospamox-DT than what is prescribed, immediately contact your doctor or the hospital and show them the packaging of the medicine.

The most common signs of overdose are: nausea, vomiting, diarrhea and abdominal pain.

If you forget to take Ospamox DT

If you forget to take a dose on time, take it as soon as you remember. Do not take a double dose to make up for the one you missed.

If you stop using Ospamox-DT

Take Ospamox DT until treatment is complete, even if you feel better. If you stop taking this medicine too soon, there may be a recurrence of the infection. Also, the bacteria can become resistant to this medicine.

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

4. POSSIBLE SIDE EFFECTS

Like any other medication, Ospamox DT can cause side effects, although not everybody gets them.

If any of the listed serious side effects occur, contact your doctor or seek help at the nearest hospital:

The following serious side effects are rare (affect less than 1 in 1000 people):

- Sudden difficulty in breathing, speaking and swallowing
- Painful swelling of the lips, tongue, face or neck
- Strongly expressed dizziness or collapse
- Severe skin rashes with itching, especially if accompanied by blisters and pain in the eyes, mouth and genital organs.
- yellowing of the skin and sclera, dark urine and stool is lighter. These are signs of the diseases of the liver.

The following side effects are very rare (affects less than 1 in 10000 people):

- Long-lasting severe diarrhea that may contain traces of blood. This may be a sign of a serious intestinal inflammation.

Other side effects:

The following side effects are common (affect less than 1 in 10 people):

- nausea, vomiting, loss of appetite, taste disturbance, dry mouth, diarrhea or loose stools. These effects are usually mild and disappear during treatment or very soon after the completion of therapy. They can be reduced by taking this medicine with food.
- Urticaria (hives), skin rash, "fifth day", which looks like measles.

The following side effects are uncommon (affect less than 1 in 100 people):

- Superinfections (sudden increase in various types of bacteria, different from the kind that is initially diagnosed and treated. This is a common cause of treatment failure, because the new species of bacteria are often resistant to primary antibiotics) caused by resistant germs or fungi (such as oral or vaginal thrush)
- Moderate rise in liver enzyme values.

The following side effects are rare (affect less than 1 in 1000 people):

- increase in the number of certain types of white blood cells (Eosinophilia), abnormal decomposition of red blood cells (hemolytic anemia)
- elevated body temperature caused by medicine
- dizziness, hyperactivity, seizures (convulsions)
- colored surface of the teeth. This coloration can be removed by washing the teeth.
- Hepatitis (an inflammatory disease of the liver) and the cholestatic jaundice (yellowing of the skin caused by the failure of bile)
- inflammation of the kidney (interstitial nephritis), the crystals in the urine.

The following side effects are very rare (affect less than 1 in 10000 people):

- changes in the blood (reducing the number of red or white blood cells and platelets), prolonged bleeding time. This can cause symptoms such as fever, sore throat, rash, nosebleed or bruises. These effects are reversible after cessation of treatment.
- Black colored tongue.

If any of the side effects worsen or you notice side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OSPAMOX DT

Keep the medicine out of reach and sight of children.

Keep at temperature up to 30 °C.

Store in the original package.

Do not use Ospamox DT after the expiry date stated on the box. The date of expiry refers to the last day of the month.

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.

Shelf life: 3 years

6. FURTHER INFORMATION

The active substance is amoxicillin.

Each Ospamox DT 500 mg tablet for oral suspension contains the amoxicillin trihydrate, corresponding to 500 mg of amoxicillin.

Each Ospamox DT 750 mg tablet for oral suspension contains the amoxicillin trihydrate, which corresponds to 750 mg of amoxicillin.

Each Ospamox DT 1000 mg tablet for oral suspension contains the amoxicillin trihydrate, which corresponds to 1000 mg amoxicillin.

Auxiliary substances:

The aroma of peach-apricot, powder

The aroma of orange blossom, powder

Magnesium stearate

Aspartame

Croscarmellose sodium

Mannitol

TALC

Anhydrous colloidal silicon dioxide

Microcrystalline cellulose

Maltodextrose

Soluble starch

Titanium dioxide

How does it look like and contents of the pack?

Ospamox DT 500 mg

Tablets for oral suspension

Ospamox DT 500 mg dispersible tablets are coated, biconvex, white to yellowish-white tablets, 8 x 18 mm, with break-mark.

Ospamox DT 500 mg tablets for oral suspension are available in a pack of 14 tablets in PVC/PVDV/Al blister packaging.

Ospamox DT 750 mg

Tablets for oral suspension

Ospamox DT 750 mg tablets for oral suspension are coated, biconvex, white to yellowish-white pills, 9 x 20 mm, with break-mark.

Ospamox DT 750 mg tablets for oral suspension are available in a pack of 14 tablets in PVC/PVDV/Al blister packaging.

Ospamox DT, 1000 mg

Tablets for oral suspension

Ospamox DT 1000 mg tablets for oral suspension are coated, biconvex, white to yellowish-white pills, 10 x 22 mm, with break-mark.

Ospamox DT 1000 mg tablets for oral suspension are available in a pack of 14 tablets in PVC/PVDV/Al blister packaging.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Lek farmacevtska družba d.d.Verovškova 57, Ljubljana, Slovenia.

Manufacturer of the medicinal product

Sandoz GmbH, Biochemiestrasse 10, Kundl, Austria