

PACKAGE LEAFLET: INFORMATION FOR THE USER

OSPEN 1000

1,000,000 IU film-coated tablets

PHENOXYMETHYLPENICILLIN

• 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 Oспен is and what it is used for
2. Before you take Oспен
3. How to take Oспен
4. Possible side effects
5. How to store Oспен
6. Further information

1. WHAT OSPEN IS AND WHAT IT IS USED FOR

Oспен is an antibiotic from the group of penicillins.

ATC code: JO1CE10.

It is intended for the treatment of angina, Scarlet fever, red wind, skin infections (pus filled scabs-impetigo), inflammation of the middle ear, paranasal cavities, pneumonia, the first stage of Lyme borreliosis (erythema migrans), and certain infections after being bitten by animals or people. We can take it for continuation of treatment which we started with injections. Oспен can prevent infections such as scarlet fever, erysipelas, rheumatic fever, endocarditis and pneumococcal infection in a person without spleen.

2. BEFORE YOU TAKE OSPEN

Do not take Oспен:

- If you are allergic (hypersensitive) to Penicillins or any of the ingredients of Oспен;
- If you have a metabolic disorder which causes malabsorption of substances from the digestive organs.

Be careful with Ospen:

- If you are hypersensitive to other medicines or other allergens, since there is a greater likelihood that you are hypersensitive to this medicine. If you experience itching, rashes, swelling of the lips, face, or heavier breathing, consult a doctor.
- If during treatment or after it you experience strong and persistent diarrhea, consult a doctor. While taking antimicrobial medicines one can develop resistant bacteria and fungi. Some can cause strong and persistent diarrhea (pseudo membranous colitis).

Taking other medicines with Ospen

Tell your doctor or pharmacist if you are taking or have recently taken any medicine, as well as those obtained without a prescription.

- Ospen can decrease the reliability of the birth control pill.
- Probenecid slows down the excretion of penicillin.
- Metoclopramide reduces the absorption of penicillin.
- do not take other antibiotics simultaneously with Ospen if they are not prescribed by a doctor.

Taking food and drinks with Ospen

No specific recommendations.

Pregnancy and breastfeeding

Consult a doctor or pharmacist before taking any medicine.

Since it is not known that the medicine is harmful during pregnancy, pregnant women can take Ospen.

The medicine is excreted in a small quantity into breast milk. During the treatment you can breastfeed. It's still possible that a child can become hypersensitive to penicillin.

Driving and using machines

Ospen has no effect on the ability to drive and use the machines.

Other warnings

The tablets contain lactose. If your doctor told you that you have intolerance to some sugars, consult your doctor before using this medicine.

Formaldehyde can cause stomach upset and diarrhea.

3. HOW TO TAKE OSPEN

Take Ospen exactly according to doctor's instructions. If you are in doubt, consult a doctor or pharmacist.

Swallow the tablet with a liquid.

The usual dose for the treatment is:

Age (body mass)	Ospen 1000 1.000.000 i. units film-coated tablets	Ospen 1500 1.500.000 i. units film-coated tablets
Adults and children heavier than 49 kg	10 to 2 tablets 3 times a day	1 tablet 3 times a day
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from 10 to 14 years (33 to 49 kg)	1 to 10 tablets 3 times a day	
from 6 to 10 years (23 to 32 kg)	1 tablet 3 times a day	
from 3 to 6 years (16 to 22 kg)	0 to 1 tablet 3 times a day	

A doctor will adjust the dose according to your disease, tolerability and response to treatment. In severe infection, a doctor may prescribe a higher dose. Ospen can be dispensed from 25000 up to 100,000 IU per kg of body weight per day in 3 to 4 doses. The highest daily dose is 6,000,000 IU.

With the inflammation of the pharynx, and mild forms of other infections, a doctor may prescribe taking two doses.

Streptococcal infection is treated for 10 days.

Prevention of infection:

Indication	Dosage
Rheumatic fever	
Adults and children heavier than 30 kg	1/2 film-coated tablets Ospen 1000 1.000.000 i. units 2 times a day
* Bacterial Endocarditis with surgery in the oral cavity	
Adults and children heavier than 30 kg 1 hour before surgery 6 Hours after initial dose	2 film-coated tablets Ospen 1500 1.500.000 i. units 1 film-coated tablet Ospen 1500 1.500.000 i. units
Children lighter than 30 kg 1 hour before surgery 6 Hours after initial dose	1 film-coated tablet Ospen 1500 1.500.000 i. units 1/2 film-coated tablet Ospen 1500 1.500.000 i. units

* For this indication Ospen is used only if it is not possible to use amoxicillin.

In case of reduced renal function (creatinine clearance less than 0.16 ml/s or 10 ml/min), the space between the two doses must be at least 8 hours.

If you take more than you should Ospen

If you have taken a higher dose than you should, consult with a doctor or pharmacist. Taking large quantities of tablets at once can cause nausea, vomiting, diarrhoea, crystalluria, and in more severe cases, increased sensitivity.

If you forget to take Ospen

Do not take a double dose if you forget to take the previous dose.

If you forget to take a dose at the scheduled time, take it as soon as you remember. Take the next dose at the usual time.

If you stop taking Ospen

If you have stopped taking Ospen before than you should, infection can reoccur.

If you have any further questions on the use of Ospen talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Ospen may cause side effects.

Side effects are classified in the following groups:

Very common	Appear in more than 1 in 10 patients
Common	Appear at 1 to 10 patients on 100 patients
Uncommon	Appear at 1 to 10 patients on 1000 patients
Rare	Appear at 1 to 10 patients on 10000 patients
Very rare	Appear at fewer than 1 patient in the 10000 patients
Unknown frequency	Not possible to evaluate from available data

Rare:

- hypersensitivity reactions, such as rash, itching, redness and hives.

Very rare:

- hypersensitivity reactions that manifest as nausea with swelling of the face, lips, throat and elsewhere on the body, suffocation and shock or urticaria, pain in the joints and swollen lymph glands.
- Strong diarrhoea, possible with blood or mucus, which lasts a long time, and that can be a sign of a special form of inflammation of the colon (of pseudo membranous colitis).

Other side effects

Common:

- nausea, vomiting and diarrhea.

Uncommon:

- While taking the medicine you may experience infection caused by resistant microbes, especially the overgrowth of Candida in the vagina.

If you notice any side effects, talk to your doctor or pharmacist.

5. HOW TO STORE OSPEN

Keep out of reach and sight of children.

Store at the temperature up to 25 ° c.

Store in the original packaging to ensure protection from moisture.

The shelf life of the medicinal product is 3 years from the date of manufacture.

Expiration date refers to the last day of that month.

Ospen must not be used after the expiry date stated on the carton.

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

6. FURTHER INFORMATION

What Ospen contains

- active substance is phenoxymethylpenicillin.

Ospen 1000 1,000,000 IU film-coated tablets

1 1,000,000 IU film-coated tablet contains 854.7 mg or 636.4 mg of phenoxymethylpenicillin in the form of benzathine-phenoxymethylpenicillinate.

Ospen 1,500,000 IU film-coated tablets

1 1,500,000 IU film-coated tablet contains 1282.0 mg or 954.6 mg of phenoxymethylpenicillin in the form of benzathine-phenoxymethylpenicillinate.

- the other substances are lactose monohydrate, the aroma of coconut, anhydrous colloidal silicon dioxide, formaldehyde casein, povidone and magnesium stearate in the Tablet core, and hypromellose (E464), titanium dioxide (E171) and talc in the film-coating.

How Ospen looks like and contents of the Pack

Ospen film-coated tablets 1000 1,000,000 IU are oval-shaped, slightly protruding, white to light gray, with cross division line on both sides. The tablet can be broken into equal halves.

Ospen film-coated tablets 1500 1,500,000 IU are oval, slightly protruding, white to light gray, with cross division line on both sides. The tablet can be broken into equal halves.

There are boxes of 30 film-coated tablets in blisters. 3 blisters of 10 tablets in the box.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

KRKA, tovarna zdravil, d.d.

Šmarješka cesta 6, Novo Mesto, Slovenia

Manufacturer of the medicinal product

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