Package leaflet: Information for the patient

Oxacillin AVMC 1000 mg powder for solution for injection/infusion
oxacillin

Read all of this leaflet carefully before you start using 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 effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What Oxacillin AVMC is and what it is used for

Oxacillin AVMC contains oxacillin as the active substance, which belongs to a group of medicines called beta-lactams, beta-lactamase-resistant penicillins.
Oxacillin acts against sensitive bacteria that cause respiratory, skin and bone infections. Oxacillin AVMC is also useful in serious infections such as endocarditis (inflammation of the inner surface of the heart), meningitis (inflammation of the meninges) and septicemia (blood poisoning). It can also be used to prevent postoperative infections.
Oxacillin can also be used for other types of infections, as recommended by your doctor.

This medicinal product is used in adults and children to treat the following infections:
- Endocarditis
- Meningitis
- Pneumonia)
- Bone and joint infections
- Osteomyelitis
- Bacteraemia associated with or suspected to be associated with the above infections
- Staphylococcal and/or streptococcal skin infections with strains susceptible to oxacillin
- Prophylaxis of postoperative infections (including neurosurgery procedures, plastic surgery etc.)

Treatment guidelines in force on the appropriate use of antibiotics should be considered.

2. What you need to know before you use Oxacillin AVMC

Do not use Oxacillin AVMC:
- If you are allergic to oxacillin, other beta-lactam antibiotics (penicillins and cephalosporins), or any of the other ingredients of this medicine (listed in section 6).

If allergic reactions occur, discontinue administration, and inform the physician.

Warnings and precautions
Talk to your doctor or pharmacist before using Oxacillin AVMC.
Any allergic manifestation that appears during treatment should be reported to your doctor immediately.

Before taking this treatment, tell your doctor if during an earlier antibiotic treatment (even with another family of antibiotics), an allergic reaction has appeared: hives or other rashes, itching, sudden swelling of the face and allergic neck (angioedema) (see section 4.).
Diarrhea may occur while taking antibiotics, including with Oxacillin AVMC, even several weeks after treatment has ended. If the diarrhea becomes severe or persists, or if you notice blood or mucus in your stool, stop taking Oxacillin AVMC immediately. Do not take medicines intended to block or slow down the intestinal transit and contact your doctor (see section 4.).

Other medicines and Oxacillin AVMC
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including methotrexate (medicine for the treatment of cancer or rheumatoid artritis), probenecid (medicine for the treatment of gout), or another antibiotic, including medicines obtained without a prescription.

Pregnancy and breast-feeding.
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.

Pregnancy
Oxacillin AVMC should not be used during pregnancy unless clearly necessary.

Breast-feeding
The passage of penicillins in breast milk is low, and the quantities ingested are much lower than the therapeutic neonatal doses. Consequently, care should be taken when oxacillin is administered to nursing mothers. If the newborn has problems such as diarrhea, rash on the skin, candidiasis (infection due to certain microscopic fungi), immediately tell your doctor who will advise you on what to do because these effects may be due to your child to this drug.

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

Driving and using machines
Oxacillin AVMC has no influence on the ability to drive and use machines.

Oxacillin AVMC contains sodium.
This medication contains approximately 64 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Oxacillin AVMC?

Dosage
Oxacillin AVMC is injectable product, it is given by a healthcare professional deep into a muscle or into a vein. The usual dose for adults, children and infants is 50-100 mg / kg daily given intravenously (IV) or intramuscularly (IM), in neonates 25-100 mg / kg daily given intravenously (IV). The doctor will determine the appropriate dose for you.

The recommended dose is:

Adults

Bacterial Infection

Mild-to-moderate infections: 250 to 500 mg into vein or into a muscle every 4 to 6 hours
Severe infections: 1 g into vein or into a muscle every 4 to 6 hours

Endocarditis (inflammation of the inner surface of the heart)

Native valve infective endocarditis: 2 g into vein every 4 hours or 3 g into vein every 6 hours. Prosthetic valve endocarditis: 2 g into vein every 4 hours. Total dose: 12 g/day
Duration of Therapy: For complicated right-sided native valve endocarditis and for left-sided native valve endocarditis: 6 weeks. For uncomplicated right-sided native valve endocarditis: 2 weeks. For prosthetic valve endocarditis: At least 6 weeks.

Joint Infections

1.5 to 2 g into vein every 4 to 6 hours

Meningitis (inflammation of meninges)

1.5 to 2 g into vein every 4 hours

Osteomyelitis (inflammation of bone marrow)

1.5 to 2 g into vein every 4 to 6 hours. Duration of therapy: 6 weeks

Skin or Soft Tissue Infection

Incisional surgical site infections: 2 g into vein every 6 hours. Skin and soft tissue infection, necrotizing infections: 1 to 2 g into vein every 4 hours

Use in children and adolescents

Premature and neonates: 12.5 mg/kg into vein or into a muscle every 8 to12 hours
Infants and children weighing up to 40 kg:
Mild to moderate infections: 12.5 mg/kg into vein or into a muscle every 6 hours
Severe infections: 25mg/kg into vein or into muscle in every 4 to 6 hours
Children weighing at least 40 kg:
Mild to moderate infections: 250 to 500 mg into vein or into a muscle every 4 to 6 hours.
Severe infections: 1 g into vein or into a muscle every 4 to 6 hours.

Endocarditis

1 year or older: 50 mg/kg into vein every 4 to 6 hours. Maximum dose: 12 g/day.
Duration of therapy: At least 4 to 6 weeks

Meningitis

Neonates 0 to 7 days: 25 mg/kg into vein every 8 to 12 hours.
Neonates 8 to 28 days:50 mg/kg into vein every 6 to 8 hours.
Infants and children: 50 mg/kg into vein every 6 hours. Maximum dose: 12 g/day

Pneumonia

Infants and children older than 3 months:50 mg/kg into vein or into a muscle every 6 to 8 hours.
Maximum dose: 12 g/day

Skin or Soft tissue infection

1 month or older:

Necrotising infections: 50 mg/kg into vein every 6 hours.
Skin and soft tissue infection: 25 to 37.5 mg/kg into vein every 6 hours

Staphylococcal Infections

Age group	**Weight**	**Dose**
Neonates up to 1 week of age	up to 1.2 kg	25 mg/kg every 12 hours
	1.2 to 2 kg	25-50 mg/kg every 12 hours
	more than 2 kg	25-50 mg/kg every 8 hours
Neonates 1-4 weeks of age	up to 1.2 kg	25 mg/kg every 12 hours
	1.2 to 2 kg	25-50 mg/kg every 8 hours
	more than 2 kg	25-50 mg/kg every 6 hours

Elderly
With intravenous administration, particularly in elderly patients, care should be taken because of the possibility of thrombophlebitis.

Renal impairment
In patients with severe renal impairment dose adjustment is required. The doctor should consider creatinine clearance and monitoring of drug levels is recommended.

Treatment should continue for at least 48 hours after resolution of signs and symptoms of infection.

Method of administration
Oxacillin is administered deep in muscle, by injection into vein or as infusion into vein, after dissolution with a compatible solvent.

Duration of the treatment
To be effective, this antibiotic must be used regularly at the prescribed doses and as long as your doctor has advised you. The disappearance of fever or any other symptom does not mean that you are completely cured. The possible feeling of tiredness is not due to the antibiotic treatment but to the infection itself. Reducing or stopping your treatment will have no effect on this feeling and will delay your recovery.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare side effects (may affect up to 1 in 1,000 people)
- elevation of certain enzymes of the liver (transaminases, alkaline phosphatases), hepatitis with jaundice

Very rare side effects (may affect up to 1 in 10,000 people)
- allergic shock (difficulty breathing, drop in blood pressure, rapid pulse)
- pseudomembranous colitis (bowel disease with diarrhea and stomach pain) (see section 2. Warnings and precautions)

Side effects with unknown frequency
- Insufficient quantity of red blood cells (anemia) or certain white blood cells (leukopenia) or cells present in the blood used for blood clotting (platelets) (thrombocytopenia) reversible with discontinuation of treatment
- Fever

- Itching, hives, discomfort in breathing, angioedema (hives with sudden infiltration of fluid in the face and neck), increase in some white blood cells in the blood (eosinophilia).
- Nausea, vomiting, diarrhea
- Kidney disease (acute interstitial nephropathy)
- Fatigability
- Neurological disorders such as impaired consciousness, confusion, abnormal movements, involuntary muscle contractions, seizures, reported after administration of large doses of oxacillin-based antibiotic, in particular in the event of kidney dysfunction.
- fungal superinfection (vaginal candidiasis)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Oxacillin AVMC

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

This medicinal product does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxacillin AVMC contains
- The active substance is oxacillin: Each vial contains 1000 mg (as oxacillin sodium monohydrate)
- The other ingredient is anhydrous disodium phosphate.

What Oxacillin AVMC looks like and contents of the pack
Oxacillin AVMC is white or almost white powder in a clear glass vial closed with grey rubber stopper and sealed with aluminium flip-off cap.
Pack size: box of 1, 10, 25 or 50 bottle(s).

Not all pack sizes may be marketed.

Marketing authorization holder
[To be completed nationally]

Manufacturer
[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic	Oxacillin AVMC
Slovakia	Oxacillin AVMC

Poland	Oxacillin Norameda
Estonia	Oxacillin Auxilia

The leaflet was last revised in

The following information is intended for healthcare professionals only:

Reconstitution and dilution

Intramuscular administration
To prepare the solution for injection for intramuscular administration, add 5.7 ml of water for injections or 0.9% sodium chloride solution to the vial.
Shake the vial until the solution is clear. The solution is given deep into the muscle immediately after preparation or within 8 hours if kept at 2-8°C.

Intravenous administration
For intravenous administration, add 10 ml of water for injections or 10 ml of 0.9% sodium chloride solution. Shake the vial until the solution is clear.
The solution should be administered slowly into vein within 10 minutes. The reconstituted solution should be used immediately or within 8 hours if kept at 2-8°C.

The reconstituted solution is further diluted with one of the following solutions for infusion:
- isotonic sodium chloride solution
- 5% glucose solution in water for injections
- 5% glucose solution in isotonic sodium chloride solution
- 10% solution of D-fructose in water for injections
- 10% solution of D-fructose in isotonic sodium chloride solution
- Ringer's solution for infusion with lactate
- solution for injection of potassium chloride and sodium chloride with lactate
- 10% solution of invert sugar in water for injections
- 10% solution of invert sugar in isotonic sodium chloride solution
- 10% solution of invert sugar + 0.3% of potassium chloride in water for injections

Chemical and physical in-use stability (as reconstituted for injection or reconstituted and diluted for infusion as described above) has been demonstrated for 8 hours at 2 – 8 °C.
From microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior use are the responsibility of the user.