Package leaflet: Information for the patient

ORLOBIN®

100 mg/2ml, 250 mg/2ml, 500 mg/2ml & 1000 mg/4ml
Solution for injection/infusion
Amikacin Sulfate

Please read all of this leaflet carefully before you start taking your medicine because it contains important information for you.
- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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 ORLOBIN is and what it is used for

The name of this medicine is ORLOBIN.
Amikacin is an antibiotic and belongs to the group of medicines called aminoglycosides.
ORLOBIN is used to treat serious infections caused by certain bacteria.

2. What you need to know before you are given ORLOBIN

Do not use ORLOBIN if:
- You are allergic (hypersensitive) to any of the ingredients in ORLOBIN or other antibiotics.
- You suffer from myasthenia gravis (a disease that causes muscle weakness).

If any of the above affects you, or you are unsure if they do, tell your doctor who will be able to advise you.
You must tell your doctor if:
- You have any kidney problems.
- You have any hearing problems or other problems with your ears.
- You have any muscular disorders such as Parkinson's Disease.

Take caution if you are elderly.
Take caution if you are dehydrated (ensure you are well hydrated during treatment).
Other medicines and ORLOBIN
Always tell your doctor or pharmacist about any other medicines you may be taking or have recently taken including those obtained without a prescription before you are given ORLOBIN. Some medicines can have an affect on the action of other medicines. It is especially important that you tell your doctor if you are taking:
- Any diuretics e.g. frusemide (water tablet or injection)
- Any antibiotics including, penicillin-type antibiotics or cephalosporins
- Any muscle relaxing medication
- Cisplatin use in the treatment of cancers
- Amphotericin B, which is used in the treatment of fungal infections
- Bisphosphonates (which are used to treat osteoporosis and similar diseases)
- Platinum compounds
- Thiamine (Vitamin B1) as it may lose its effectiveness
- Any other medicines which are bad for your kidneys or hearing
- Indomethacin (an anti-inflammatory). This can increase the amount of ORLOBIN which is absorbed in new born babies

Or
- If you have recently received an anaesthetic.

ORLOBIN is not recommended to be given by injection into the stomach in young children.
Pregnancy and breast-feeding
If you are pregnant or breast-feeding, or think you may be pregnant, you should speak to your doctor before you are given ORLOBIN.
Driving and using machines
If you feel unwell or suffer from any of the side effects do not drive or operate machinery.
ORLOBIN contains sodium bisulphite
ORLOBIN Solution for injection/infusion contains the inactive ingredient sodium bisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm (difficulty in breathing or wheezing).

3. How ORLOBIN is given

ORLOBIN is given by injection into a muscle or vein, or occasionally into the abdomen. The patient's pre-treatment body weight should be obtained in order to calculate the correct dosage. The usual duration of the treatment is 7 to 10 days. The total daily dose by all routes of administration should not exceed 15-20 mg/kg/day.
Adults and children over 12 years: The usual dose is 15 mg/kg/day which is given once a day or divided into two doses which are given twice a day.
Elderly: Renal function should be assessed and dose adjusted as described under impaired renal function.
Children aged 4 weeks to 12 years: The usual dose is 15 – 20 mg/kg/day which is given once a day or divided into two doses which are given twice a day.
Neonates: The usual dose is initially 10 mg/kg followed by 7.5 mg/kg which is given twice a day.
Premature infants: The usual dose is 7.5 mg/kg twice a day.
Life-threatening infection and/or those caused by Pseudomonas: The doses may be increased to 500 mg every eight hours, but should not exceed 1.5 g/day or be administered for a period longer than 10 days.
Urinary tract infections: The usual dose is 7.5 mg/kg/day twice a day.
Impaired renal function: The daily dose should be reduced and/or the interval between doses increased to avoid build up of drug.
The doses may be increased in certain infections.
You may require hearing and kidney tests while receiving ORLOBIN as well as blood tests to check the amount of amikacin received.
You should start to see an improvement in 1-2 days. If there has been no improvement after 3-5 days, go back to see your doctor.
If you are given too much or too little ORLOBIN Solution for injection/infusion
ORLOBIN Solution for injection/infusion will be given by a qualified healthcare professional (doctor or nurse) who will ensure you are given the correct dose. On rare occasions, you may be given too much ORLOBIN Solution for injection/infusion. If this happens, your doctor will make sure that it is removed from your blood so that
you do not suffer too many side effects.

4. Possible side effects

As with all medicines, ORLOBIN can cause unwanted side effects, although not everybody gets them.
If you notice any of the following, stop taking ORLOBIN and contact your doctor immediately:
- swelling of the face, lips, or tongue
- skin rash
- difficulty breathing

As these may be signs of an allergic reaction.
The frequency of possible side effects listed below is defined using the following convention:

very common:	affects more than 1 user in 10
common:	affects 1 to less than 10 users in 100
uncommon:	affects 1 to less than 10 users in 1,000
rare:	affects 1 to less than 10 users in 10,000
very rare:	affects less than 1 user in 10,000

Patients treated with ORLOBIN have reported the following side effects:
Uncommon
- feeling sick (nausea) and being sick (vomiting)
- skin rash
- infections with resistant bacteria or yeasts

Rare
- abnormal white blood cells, which can be detected by blood tests
- reduced magnesium levels in the blood
- headache
- tremor
- muscle twitching
- pins and needles

- numbness
- blindness or other problems with your vision
- low blood pressure
- ringing in the ears
- loss of hearing
- joint pain
- itching and hives
- kidney problems including a reduction in urine output and increased nitrogen in the urine
- fever
- dizziness
- anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)

Other side effects where the frequencies are unknown include:
- inability of muscles to move
- wheezing, difficulty breathing
- temporarily stopping breathing
- deafness

On rare occasions, it may be necessary to inject ORLOBIN directly into the eyeball which can lead to visual disturbances.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your medicine

Do not store above 25°C.
Store in the original packaging.
Please check the expiry date of the product, shown on the packaging of ORLOBIN.
Do not use after the last day of the month stated.
Do not use this medicine if it is discoloured or there are particles in the solution.
Keep out of the sight and reach of children.
The vial is to be used once only. Any unused solution in the vial should be thrown away.
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 ORLOBIN contains

ORLOBIN 100 mg/2ml solution for injection/infusion: Each 2ml vial contains amikacin sulfate (equivalent to amikacin activity 100 mg) as the active ingredient.
ORLOBIN 250 mg/2ml solution for injection/infusion: Each 2ml vial contains amikacin sulfate (equivalent to amikacin activity 250 mg) as the active ingredient.
ORLOBIN 500 mg/2ml solution for injection/infusion: Each 2ml vial contains amikacin sulfate (equivalent to amikacin activity 500 mg) as the active ingredient.
ORLOBIN 1000 mg/4ml solution for injection/infusion: Each 4ml vial contains amikacin sulfate (equivalent to amikacin activity 1000 mg) as the active ingredient.
In addition, ORLOBIN contains the following inactive ingredients: sodium bisulphite, sodium citrate, sulphuric acid and water for injection.

What ORLOBIN looks like and contents of the pack

ORLOBIN Solution for injection/infusion is a colorless to yellowish, practically free of particles, aqueous solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

MEDICUS S.A., 10 Valaoritou str., GR 144 52, Metamorphosis, Attika - Greece, Tel.: 0030 210 281 9431

Manufacturer

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INFORMATION FOR HEALTH PROFESSIONALS

Below is a summary of the dosage and administration of ORLOBIN. Reference should be made to the Summary of Product Characteristics (SmPC) for full prescribing information.

DOSAGE AND ADMINISTRATION

At the recommended dosage level, uncomplicated infections due to sensitive organisms should respond to therapy within 24 to 48 hours. If clinical response does not occur within three to five days consideration should be given to alternative therapy.

Intramuscular or intravenous administration:
For most infections the intramuscular route is preferred, but in life-threatening infections, or in patients in whom intramuscular injection is not feasible, the intravenous route, either slow bolus (2 to 3 minutes) or infusion (0.25% over 30 minutes) may be used.

Adults and children over 12 years:
The recommended intramuscular or intravenous dosage for adults and adolescents with normal renal function (creatinine clearance ≥ 50 ml/min) is 15 mg/kg/day which may be administered as a single daily dose or divided into 2 equal doses i.e. 7.5 mg/kg every 12 hours. The total daily dose should not exceed 1.5 g. In endocarditis and in febrile neutropenic patients dosing should be twice daily, as there is not enough data to support once daily dosing.

Children 4 weeks to 12 years:
The recommended intramuscular or intravenous (slow intravenous infusion) dose in children with normal renal function is 15-20 mg/kg/day which may be administered as 15-20 mg/kg, once a day; or as 7.5 mg/kg every 12 hours. In endocarditis and in febrile neutropenic patients dosing should be twice daily, as there is not enough data to support once daily dosing.

Neonates:
An initial loading dose of 10 mg/kg followed by 7.5 mg/kg every12 hours.

Premature infants:
The recommended dose in premature infants is 7.5 mg/kg in every 12 hours.

Aminoglycosides should be used with caution in premature and neonatal infants because of the renal immaturity of these patients and the resulting prolongation of serum half-life of these drugs.

Specific recommendation for intravenous administration:
The solution for intravenous use should be prepared by adding the desired dose to 100ml or 200ml of sterile diluent such as normal saline or 5% dextrose in water or any other compatible solution. In paediatric patients the amount of diluents used will depend on the amount of amikacin tolerated by the patient. The solution should normally be infused over a 30 to 60 minute period. Infants should receive a 1 to 2 hour infusion.

Life-threatening infections and/or those caused by Pseudomonas:
The adult dose may be increased to 500 mg every eight hours but should neither exceed 1.5 g/day nor be administered for a period longer than 10 days. A maximum total adult dose of 15 g should not be exceeded.

Urinary tract infections (other than pseudomonal infections):
7.5 mg/kg/day in equally divided doses (equivalent to 250 mg twice a day in adults). As the activity of amikacin is enhanced by increasing the pH, a urinary alkalising agent may be administered concurrently.

Impaired renal function:
In patients with impaired renal function, the daily dose should be reduced and/or the intervals between doses increased to avoid accumulation of the drug. The critical serum creatinine concentration is 1.5 mg/100 ml. A suggested method for estimating dosage in patients with known or suspected diminished renal function is to multiply the serum creatinine clearance (in mg/100 ml) by 9 and use the resulting figure as the interval in hours between doses.
As renal function may alter appreciably during therapy, the serum creatinine should be checked frequently and the dosage regimen modified as necessary. Body fluid specimens taken for testing should be assayed promptly, frozen or treated with beta lactamase, to avoid the continued inactivation of the aminoglycoside leading to inaccurate readings.

Other Routes of Administration:
ORLOBIN in concentrations of 0.25% (2.5 mg/ml) may be used satisfactorily as an irrigating solution in abscess cavities, the pleural space, the peritoneum and the cerebral ventricles.

MEDICUS PHARMACEUTICALS

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