Package leaflet: Information for the user

Tobramycin 40 mg/ml Solution for Injection
tobramycin

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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tobramycin is and what it is used for

Tobramycin is an antibiotic medicine (used to fight infections caused by bacteria).

Tobramycin can be used to treat:
- infections of the brain and spinal cord, e.g. meningitis
- infections of the stomach or intestines
- infections of the bladder or kidney (urinary tract infection)
- infections of the lungs, e.g. pneumonia
- infections of the bone, skin or soft tissue including burns

2. What you need to know before you use Tobramycin

Tobramycin must never be injected intrathecally (into the spine).

Do not use Tobramycin:
- if you are allergic to tobramycin or any of the other ingredients of this medicine (listed in section 6), or similar medicines (called aminoglycosides)
- if you are pregnant or breast feeding
- if you are taking potent diuretics (water tablets) such as frusemide or ethacrynic acid

Tell your doctor if the above applies to you before this medicine is used.

Warnings and precautions

Talk to your doctor or nurse before using Tobramycin:
- if you or your family members have a mitochondrial mutation disease (condition caused by variants in the genome of mitochondria, the parts of your cells which help make energy) or loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product

- if you have muscle disorders, such as myasthenia gravis (a disease in which the muscles become weak and tire easily) or parkinsonism (a disease of the brain which affects movement)
- if you have kidney trouble
- if you have severe burns
- if you have endocarditis (an inflammation inside the heart)
- if you have neutropenia (a low number of white blood cells)
- if you are of advanced age
- if you are dehydrated

Special care is also needed if this medicine is to be given to babies or infants less than 6 weeks of age, or if you have received a large blood transfusion or if you have cystic fibrosis.

Other medicines and Tobramycin
Special care is needed if you are taking/using other medicines as some could interact with Tobramycin, for example:

- aminoglycosides (e.g. amikacin, streptomycin, neomycin, kanamycin, gentamicin, paromomycin)
- some other antibiotics (e.g. cephalothin)
- amphotericin B (a medicine used to treat fungal infection)
- some diuretics (water tablets)
- medicines used as general anaesthetics
- medicines used as muscle relaxants during general anaesthesia
- cisplatin (anti-cancer medicine)
- ciclosporin (a medicine that reduces the activity of the body's immune system)
- neostigmine and pyridostigmine (medicines used in the treatment of muscle weakness)
- other drugs (e.g. warfarin and phenindione)

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There may be a risk of birth defects if this medicine is used during pregnancy and some children whose mothers took similar medicines (streptomycin, kanamycin and gentamicin) have been born deaf. It will only be used if the potential benefits clearly outweigh the risks.

Driving and using machines
Do not drive or use machines if you experience any side effect (e.g. dizziness or drowsiness) which may lessen your ability to do so.

Tobramycin Solution for Injection contains Sodium metabisulphite and sodium.

Tobramycin contains sodium metabisulphite. May rarely cause severe hypersensitivity reactions and bronchospasm.

Tobramycin Solution for Injection contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. How to use Tobramycin

This medicine is given by injection (using a syringe) into a muscle or a vein, or infusion (drip) into a vein.

If it is given as an infusion it will be diluted before use. It will then be infused over a 20 to 60 minute period.

Dose
Your doctor will work out the correct dose of Tobramycin for you and how often it must be given.

The dose will depend on your medical condition, your size, how serious the infection is, your age and how well your kidneys are working. Your doctor will tell how well your kidneys are working using blood or urine samples.

Treatment normally lasts for 7 to 10 days. If you take tobramycin for more than 10 days or take more than the recommended dose, you may experience more severe side effects. These include dangerous breathing difficulties, which could also occur if you do not drink enough fluid, if you have poor kidney function or if you are taking other drugs that can affect your hearing.

Your doctor may take regular blood samples to ensure you are receiving the correct dose.

If you are given too much or too little Tobramycin Solution for Injection
This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

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

If any of the following happen, tell your doctor immediately:
- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- loss of hearing
- ringing, buzzing or roaring noise in your ears
- dizziness
- vertigo (a feeling that you or your surroundings are spinning)

These are serious side effects. You may need urgent medical attention.

If any of the following happen, tell your doctor as soon as possible:
Common: may affect up to 1 in 10 people
- pain or reaction at the injection site
- swelling, redness and tenderness along a vein
- change in levels of white cells in the blood
- changes in urine function, passing more urine that usual

Uncommon: may affect up to 1 in 100 people
- increase in levels of white blood cells

- headache
- cough
- hoarseness or difficulty speaking
- sore throat
- difficulty in breathing
- noisy breathing
- feeling or being sick
- rash or development of raised coloured blotches
- itching

Rare: may affect up to 1 in 1,000 people
- confusion and disorientation
- increased sputum quantities or coughing up blood
- diarrhoea
- fever (high temperature)
- feeling tired or drowsy
- palpitations
- blurred vision
- prickling sensation in arms or legs, 'pins and needles'
- anaemia (reduction in red blood cells which can make the skin pale)
- low white blood cells (which may make you more prone to infections)
- reduction in blood platelets which increases the risk of bleeding or bruising

Very rare: may affect up to 1 in 10,000 people
- convulsions or muscle twitching
- loss of strength

Not known: frequency cannot be estimated from the available data
- oral or genital fungal infections
- a state of near-unconsciousness

Tobramycin may cause kidney damage (the damage may range from mild renal impairment to acute renal failure). Your doctor may take blood samples to monitor for this.

Tobramycin may lead to changes in your blood cells. Your doctor may take blood samples to check the number of cells and levels of electrolytes in your blood, which can become low.

Your doctor may also check for hearing problems. The loss of hearing is usually irreversible.

Some patients who have received an injection of tobramycin into the eye have experienced serious vision problems. This is not a recommended use of this medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance. Website: www.hpra.ie.

Malta
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal

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

5. How to store Tobramycin

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 vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if the solution is not clear and colourless.

Do not store above 25°C. Keep the vial in the outer carton in order to protect from light.

Unused portions of opened vials must not be stored for later use.

Prepared infusions should be used immediately, however, if this is not possible they can be stored for up to 24 hours at 2 - 8ºC provided they have been prepared in a way to exclude microbial contamination.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Tobramycin Solution for Injection contains
The active substance is tobramycin. Each millilitre (ml) of solution contains 40 milligrams (mg) of tobramycin.

The other ingredients are sodium metabisulphite (E223), disodium edetate, sulphuric acid (E513) (for pH adjustment), sodium hydroxide (for pH adjustment) and Water for Injections (see section 2 **Tobramycin Solution for Injection contains Sodium metabisulphite and sodium**).

What Tobramycin Solution for Injection looks like and contents of the pack
Tobramycin is a clear colourless solution for injection presented in glass containers called vials.

It may be supplied in packs containing:
- 5 x 40 mg/1 ml vials
- 5 x 80 mg/2 ml vials
- 1 or 5 x 240 mg/6 ml vials

Not all packs may be marketed.

Marketing authorisation holder:

Ireland:
Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland

Malta:
Pfizer Hellas S.A.
243 Messoghion Ave.
154 51 N. Psychiko
Greece

Manufacturer:

Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium.

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Tobramycin 40 mg/ml Solution for Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Incompatibility or loss of activity has been reported between tobramycin sulphate and some cephalosporins and penicillins and also heparin sodium. Solutions with clindamycin phosphate in glucose injection are reported to be unstable.

Tobramycin Solution for Injection should not be physically premixed with other drugs but should be administered separately according to the recommended dose and route.

Instructions for use and handling

Tobramycin must never be injected intrathecally (into the spine).

Single use only.

Discard any unused contents.

When given by infusion, Tobramycin Solution for Injection may be diluted (with 0.9% Sodium Chloride Intravenous Infusion or 5% Dextrose Intravenous Infusion) to volumes of 50-100 ml for adult doses. For children, the volume of diluent should be proportionately less than for adults.

After dilution, chemical and physical in-use stability has been demonstrated in dextrose 5% and sodium chloride 0.9% infusion solutions for 24 hours at 24°C in the presence of light.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.