Package leaflet: Information for the patient

Capreomycin Injection

Capreomycin

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Capreomycin Injection is and what it is used for
- 2. What you need to know before you are given Capreomycin Injection
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1. What Capreomycin Injection is and what it is used for

Capreomycin Injection contains the active ingredient capreomycin, which is an antibiotic.

Capreomycin is used to treat tuberculosis (TB) together with other medicines.

2. What you need to know before you are given Capreomycin Injection

Do not use Capreomycin Injection:

- If you are allergic to capreomycin. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Capreomycin Injection should not be given to children.

Warnings and precautions

Talk to your doctor before being given Capreomycin Injection

- If you have kidney problems
- If you are hard of hearing. Your doctor may want to test your ears before you have Capreomycin Injection.
- If you have a history of allergies, especially to other medicines

If you suffer from any of the above, tell your doctor.

Taking other medicines and Capreomycin Injection

Tell your doctor if you are taking, have recently taken or might take, any other medicines, including medicines obtained without a prescription. In particular, talk to your doctor if you are using any of the following medicines:

- streptomycin, viomycin (other treatments for tuberculosis [TB])
- polymyxin, colistin sulphate, amikacin, gentamicin, tobramycin, vancomycin, kanamycin and neomycin (anti-infective agents)

It may still be all right for you to be given Capreomycin Injection and your doctor will be able to decide what is suitable for you.

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 for advice before being given this medicine.

Driving and using machines

In large doses, Capreomycin may cause muscle weakness or certain muscles not to work and so affect your ability to drive or use machines. Use caution when driving or operating heavy machinery until you are aware of how this drug affects you.

3. How you are given Capreomycin Injection

Capreomycin Injection will be given to you by a doctor or nurse.

Dosage

The recommended dose: 1 gram of Capreomycin is injected every day for up to 4 months. After that, you may be given 1 gram two or three times a week.

Capreomycin should only be injected into a muscle.

If you have kidney problems your doctor may reduce your dose.

You will be given other TB antibiotic medicines while you are having Capreomycin Injection.

Use in children

Capreomycin Injection should not be given to children.

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

4. Possible side effects

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

Very serious side effects

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching, especially affecting your whole body.

The following very serious side effects have been reported:

- kidney or liver problems (signs and symptons are weakness and fatigue, weight loss, nausea, vomiting and yellow discolouration of the skin (jaundice))
- the amount of potassium in your blood may decrease (signs and symptoms are muscle weakness, muscle cramps, feeling thirsty all the time, drinking all the time, urinating frequently, vomiting and, possibly, having a fit)

Other reported side effects:

- hearing or balance may get worse and you may have noises in your ears or feel dizzy
- changes in the number of different types of blood cells (a blood test carried out by a doctor will detect these). You may notice that you bruise easily (caused by low platelets) or are unable to fight off infections
- rash (without other symptoms)
- itching
- injection site pain, bleeding or development of lumps in the skin where injected
- fever

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: <u>www.mhra.gov.uk/yellowcard</u>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Capreomycin Injection

Your doctor or pharmacist knows how to store Capreomycin Injection.

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 label after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Reconstituted solutions may be stored below 25°C for 24 hours. Discard unused portion.

Do not throw away any medicines via wastewater or household waste.

6. Contents of the pack and other information

What Capreomycin Injection contains:

Each vial contains capreomycin sulphate (approximately equivalent to 1g Capreomycin base)

What Capreomycin Injection looks like and contents of the pack

Capreomycin Injection is provided as a sterile white powder for solution for injection in rubber stoppered, clear glass vial, with aluminium or plastic seals.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in October 2021