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Gentamicin Sulphate Injection IP

GENTACAN INJECTION

For IM / IV Use

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

What is in this leaflet

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2. What you need to know before you are given Gentamicin 40mg/ml Injection.
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1. What Gentamicin 40mg/ml Injection is and what it is used for

The name of your medicine is Gentamicin 40mg/ml Injection. Gentamicin 40mg/ml Injection contains the active ingredient gentamicin which belongs to a group of medicines called antibiotics. Gentamicin 40mg/ml Injection is used in adults and children to treat bacterial infections such as severe chest infections, urinary tract infections, and septicaemia.

2. What you need to know before you are given Gentamicin 40mg/ml Injection

You should not be given Gentamicin 40mg/ml Injection: if you are allergic to gentamicin or a similar medicine containing an aminoglycoside antibiotic, or any of the other ingredients of this medicine, if you suffer from myasthenia gravis, a disease-causing muscle weakn

Warnings and precautions

Talk to your doctor or nurse before being given Gentamicin 40mg/ml Injection: if you have any problems with your kidneys, liver or hearing, if you have any infections or a fever, if you have low blood pressure or low blood volume, if you are considered to be significantly overweight, if you have Parkinson's disease or any other disease-causing muscle weakness, if you are pregnant or think you may be pregnant. If any of these apply to you, or if you are not sure, tell your doctor. Monitoring during treatment your doctor may want to send you for blood tests from time to time to check the levels of gentamicin in your blood. This is because your doctor may need to keep a careful eye on you during your treatment to prevent damage to your ears. If you are over 65 years of age or the patient is under 1 year of age, they may also monitor your hearing, your balance, and how your kidneys and liver are working. Other medicines and Gentamicin 40mg/ml Injection. Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines. This is especially important if you are taking: Antibiotics such as penicillin, ticarcillin, clindamycin, lincomycin, cephalosporins, vancomycin or other aminoglycoside antibiotics Cyclosporine (used to stop the body rejecting bone marrow or organ transplants) Cisplatin and fludarabine (chemotherapy drugs) Amphotericin (used to treat fungal infections) Furosemide (frusemide) and piretanide (used to treat heart problems) Muscle relaxant medicines used to treat myasthenia gravis such as neostigmine and pyridostigmine Indomethacin (an anti-inflammatory) Bisphosphonates (used to treat osteoporosis).

Pregnancy and breastfeeding: if you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before being given this medicine. Pregnancy Gentamicin is not recommended for use in pregnancy unless considered appropriate by your doctor. Breast-feeding: Use or Gentamicin 40mg/ml Injection whilst breastfeeding is not recommended if you are suffering from kidney problems. Driving and using machines: This medicine should not affect your ability to drive or use machines.

3. How you will be given Gentamicin 40mg/ml Injection

This medicine will be given to you by a doctor or nurse as an injection into a muscle or vein. It can also be given as a drip (infusion). Your doctor will work out the dose which is suitable for you. The recommended dose in adults with normal kidney function is 3 - 6 mg/kg of body weight per day as one (preferred) up to two single doses. Your doctor may increase the dose, or frequency of doses, based on your condition.

Use in children and adolescents: The recommended dose in children aged 1 year and above and adolescents with normal renal function is 3 - 6 mg/kg of body weight per day as one (preferred) up to two single doses. Use in infants after the first month of life The daily dose in infants after the first month of life is 4.5 - 7.5 mg/kg of body weight per day as one(preferred) up to two single doses.

Use in newborns: The daily dose in newborns is 4-7 mg/kg of body weight per day. Due to the longer half-life, newborns are given the required daily dose in one single dose.

Use in the elderly: The dose for the elderly will be adjusted accordingly.

Use in patients with kidney problems: The dose for patients with kidney problems will be adjusted accordingly. If you are given more Gentamicin 40mg/ml Injection than you should overdosing is unlikely. If it does happen the doctor will treat any symptoms that follow. Symptoms of overdose include dizziness, a feeling of spinning, and hearing loss. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice: itching or skin rashes swelling of the face, lips, throat difficulty in breathing, or wheeziness, tell your doctor immediately. These may be signs of an allergic reaction. Tell your doctor or nurse immediately if you experience: Problems with your kidney function difficulty in breathing following surgery Muscle weakness. Other side effects include: Uncommon (may affect up to 1 in100 people): Feeling or being sick sore mouth.

Problems with your liver blood disorders: Rare (may affect up to 1 in 1,000 people): Diarrhoea, Stomach pain and electrolyte disturbances (changes in the levels of salts in the blood). Very rare (may affect up to 1 in10,000 people): Problems with your brain Fits, confusion, hallucinations, tiredness, and depression.

Acute kidney failure: High urine levels of phosphate and amino acids (so-called Fanconi-like syndrome, associated with high doses given over a long time). Not known (frequency cannot be estimated from the available data) Symptoms of increased urination, swelling in legs, ankles, breathlessness, loss of appetite, sleeping difficulty. These could be a sign of kidney failure.

Reduction in red blood cells can make the skin pale and cause weakness or breathlessness symptoms of bruising, discoloration of the skin, small red spots. These could be a sign of purpura problems with your ears that causes a loss of balance Irreversible hearing loss, deafness.

5. How to store Gentamicin 40mg/ml Injection:

Keep this medicine out of sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton after the Expiry Date. Store in a cool place. Store Protected from light.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 Gentamicin 40mg/ml Injection contains: The active substance is Gentamicin sulphate. Each ml ampoule contains Gentamicin sulphate (equivalent to Gentamicin base) 40 mg. The other ingredients are Methyl Paraben IP 1.8mg Propyl Paraben IP 0.2mg (as preservative) and water for Injection. What Gentamicin 40mg/ml Injection looks like and the content of the pack Gentamicin 40mg/ml Injection is a clear colorless solution. It is available in 2 ml clear glass ampoules in boxes of 10 x 2 ml ampoules.

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