Sodium fusidate 500 mg for intravenous infusion

Sodium fusidate infusion is used to treat infections such as:
- Infections of the skin and wounds
- Infections of the lungs such as pneumonia
- Infections of the bone and heart
- Infections of the blood such as septicaemia
- Infections of the brain
- Cystic fibrosis

Sodium fusidate is a type of antibiotic. This medicine contains sodium fusidate. It is a type of antibiotic.

Powder for reconstitution and use as an intravenous infusion.

1. What sodium fusidate infusion is and what it is used for
Sodium fusidate 500 mg for intravenous infusion contains:
- Sodium. Each reconstituted vial contains 73 milligrams (mg) of sodium fusidate.
- Disodium hydrogen phosphate, citric acid, disodium edetate and water for injections. (When reconstituted with sodium fusidate dry powder vial contains 3.1 mMol sodium and 1.1 mMol phosphate).

2. Before you have sodium fusidate infusion
Do not have sodium fusidate infusion:
- If you have problems with your liver
- If you are allergic (hypersensitive) to sodium fusidate or any of these ingredients in section 6 of this leaflet.

Take special care with sodium fusidate infusion:
Before you have sodium fusidate infusion, tell your doctor:
- If you are taking statins (medicines to lower blood cholesterol) as your doctor may need to change your dose.
- If you are taking oral anti-coagulants (medicines to “thin” your blood). You may be at risk of bleeding more easily. Your doctor may need to change your dose.
- If you are breast-feeding.

3. How to use sodium fusidate infusion
For children and adults weighing less than 50 kg: Add the 10 ml sodium fusidate powder (equivalent to 480 mg of fusidic acid) in the 10 ml sterile phosphate-citrate buffer solution (pH 7.4 - 7.6) provided and added to 500 ml of infusion fluid, the shelf-life of this solution is 24 hours.

The diluted fluid should be infused via a central venous line over 2 hours. If a superficial vein is used a more prolonged period of at least 6 hours is advisable.

4. Possible side effects
These may include:
- Skin reaction such as itching, redness or rash
- Muscle pain
- Pain at the site of injection

Report any side effect to your doctor, even if you think it may be unrelated to this medicine. It may harm them, even if their symptoms are the same as yours.

5. How to store sodium fusidate infusion
Sodium fusidate dry powder is stable from light.

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sodium. You should take this into consideration if you are on a
controlled sodium diet. Please ask your doctor if you are unsure
about any of the ingredients in this medicine.

3. HOW TO USE SODIUM FUSIDATE INJECTION
Sodium fusidate infusion will be given to you by a doctor or nurse.
How much sodium fusidate infusion to have
Your doctor will prescribe the right dose for you.
If you have received more sodium fusidate infusion than you should
Your doctor or nurse will give you this medicine. If you think that you have
been given too much, tell your doctor or nurse straight away.
If you have missed a dose of sodium fusidate infusion
You should ask your doctor or nurse for the next dose of medicine.
If you have any further questions about using this medicine, please
ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, sodium fusidate infusion can cause side effects, although
not everybody gets them. Approximate the number of people who may experience side effects with sodium fusidate infusion, but many of
these are where the medicine is given into the vein.
Serious side effects
Rare (affects less than 1 in 1000 people; allergic reaction. You must
generally stop treatment if you have any of the following symptoms:
• You have difficulty breathing
• You develop swelling in your face
• You develop a severe rash.
Number of people affected not known:
• You have any of the following symptoms:
• You develop muscle weakness
• You develop muscle pain
• You develop muscle tenderness.
Common side effects
In 1 in 100 people: problems with your liver:
You should tell your doctor straight away if you have the following symptoms:
• Your skin or the whites of your eyes appear yellow.
Number of people affected not known:
• You have any of the following symptoms:
• You develop muscle weakness
• You are unwell.
Number of people affected not known: You must get urgent medical
care immediately if you have any of the following symptoms:
• Pain or inflammation of the vein
• Your blood may change. You should tell your doctor straight away if you have any of the following symptoms:
• You develop any unexplained bleeding
• You develop persistent or repeated mouth ulcers, sore
• Thrums or other infections.
Other possible side effects:
Common (affect less than 1 in 10 people)
• Pain or inflammation of the vein when the sodium fusidate infusion is given, dizziness, drowsiness.
Uncommon (affect less than 1 in 100 people)
• Headache, rash, itchy rash, itching, a feeling of unwellness, feeling tired, weak or unwell.
If any of the side effects become severe or you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE SODIUM FUSIDATE INJECTION
• Keep out of the reach of the
• Do not use sodium fusidate infusion after the expiry date on
the carton. The expiry date is the last day of that month.

6. FURTHER INFORMATION
What sodium fusidate infusion contains
• The other ingredients are citric acid, disodium edetate, sodium citrate, phosphoric acid and water for injections.
You can find important information about some of the ingredients in
your medicine near the end of section 2 of this leaflet.
What sodium fusidate infusion looks like and contents of the pack
Sodium fusidate infusion comes in packs of 2 vials. One vial contains
the sodium fusidate (powder) and the other vial the solution for infusion.
Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: LEO Laboratories Limited, Princes
Road, Wrexham, Clwyd, CH9 3TF, UK.
Manufacturer: LEO Pharma A/S, DK 2750 Ballerup, Denmark.
This leaflet was last revised in
January 2012.
This leaflet was last approved in January 2012.

This product should be administered intravenously into a wide bore vein with
a large needle. Flow error. Excess flow may cause tissue damage,
thrombophlebitis and haemorragies of erythrocytes. Both oral and intravenous presentations have been given concurrently with other antibiotics, e.g. cloxacillin, flucloxacillin, ampicillin, methicillin and erythromycin.
If additional antibacterial therapy is to be employed, it is recommended
that for parenteral administration, separate infusion fluids be
employed.
This product should not be infused with amino acid solutions or in whole
blood.
In vitro compatibility studies of Sodium Fusidate 500 mg for Intravenous
Infusion with commonly used infusion solutions have been carried out.
The results showed that sodium fusidate reconstituted at 50 mg/ml in
buffer solution is physically compatible with the following infusion
components (the figure in parenthesis shows the concentration of sodium fusidate in the final
admixture):
Sodium Chloride Intravenous Infusion BP 0.9% (1-2 mg/ml)
Disodium Edetate Intravenous Infusion BP 9% (0.0009 mg/ml)
Compound Sodium Lactate Intravenous Infusion (“Ringer’s Lactate
Sodium Infusion BP”)
Sodium Lactate Intravenous Infusion BP 1 mg/ml
Sodium Chloride (0.18%) and Dextrose (4%) Intravenous Infusion BP 1
(vial) and Water for Injections (vial)
Potassium Chloride (0.3%) and Dextrose (5%) Intravenous Infusion BP 1
(vial) and Water for Injections (vial)
Sodium fusidate reconstituted at 50 mg/ml in buffer solution is physically incompatible with infusion fluids containing 20% or more of dextrose, lipid infusions, amino acid solutions or dialysis fluids. Precipitation may occur at dilutions which result in a pH of less than 7.4.
Further information can be found in the Summary of Product
Characteristics or from: LEO Pharma, Longwood Road, Princes Risborough,
Buckinghamshire, HP27 9RR.