Package leaflet: Information for the user

Sodium Fusidate 500 mg for Intravenous Infusion

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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms 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. See section 4.
- In this leaflet Sodium Fusidate 500 mg for Intravenous Infusion will be called sodium fusidate infusion.

What is in this leaflet:

1. What sodium fusidate infusion is and what it is used for

This medicine contains sodium fusidate. It is a type of antibiotic.
Sodium fusidate infusion works by killing germs (bacteria) that cause infections.
Sodium fusidate infusion is used to treat infections such as:

- Infections of the skin and wounds
- Infections of the blood such as septicaemia
- Infections of the bone and heart tissue
- Infections of the lungs such as pneumonia
- Infections connected with the condition cystic fibrosis.

2. What you need to know before you use sodium fusidate infusion

Do not use sodium fusidate infusion

- If you are allergic to fusidic acid or its salts or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Before you use sodium fusidate infusion, tell your doctor:

- If you are taking statins (medicines to lower blood cholesterol).
- If you have problems with your liver.
- If you have recently been jaundiced.

When you are using sodium fusidate infusion your doctor may take regular blood tests in patients on high doses, with liver or bile problems, taking the medicine for a long time or taking other medicines that affect the liver.

If you are concerned that your treatment is not as effective as it should be, tell your doctor. As with any antibiotic treatment, long term or repeated use may increase the risk of developing antibiotic resistance.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of sodium fusidate.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- DRESS appears initially as flu-like symptoms and a rash on the face, then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- The highest risk for occurrence of serious skin reactions is within 8 weeks of treatment. If you develop a serious rash or another of these skin symptoms, stop taking sodium fusidate and contact your doctor or seek medical attention immediately.

Other medicines and sodium fusidate infusion
Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

- Do not take statins (medicines to lower blood cholesterol) while using this medicine.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Other antibiotics, such as lincomycin and rifampicin.
- Oral anti-coagulants (medicines to "thin" your blood). You may be likely to bleed more easily. Your doctor may need to change your dose.
- Medicines to lower blood cholesterol, such as statins. This may lead to muscle weakness, tenderness or pain. Also see section 4 of this leaflet.
- Ritonavir or saquinavir, medicines used to treat HIV.
- Ciclosporin. This medicine is used to reduce the body's immune reactions.

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 or pharmacist for advice before taking this medicine.

Driving and using machines
Usually your medicine will have very little effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Sodium fusidate infusion contains sodium
This medicine contains 72.6 mg sodium (main component of cooking/table salt) in each reconstituted vial. This is equivalent to 3.6% of the recommended maximum daily dietary intake of sodium for an adult. You should take this into consideration if you are on a controlled sodium diet.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. How to use sodium fusidate infusion

Sodium fusidate infusion will be given to you into your vein 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 you may have been given too much, tell your doctor or nurse straight away.

If you have missed a dose of sodium fusidate infusion

Your doctor or nurse will give you this medicine. If you think that you have missed a dose then tell your doctor or nurse.
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.
Approximately 3 out of 10 people 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 1,000 people): allergic reaction. You must get urgent medical help if you have any of the following symptoms:

- You have difficulty breathing
- Your face or throat swell
- Your skin develops a severe rash.

Number of people affected not known: You must get urgent medical help if you have any of the following symptoms. You may be developing a condition called rhabdomyolysis:

- You develop muscle weakness
- You develop muscle pain
- You develop muscle tenderness.

Common: affects less than 1 in 10 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: problems with your kidneys.
You should tell your doctor straight away if you have the following symptoms:

- You are not passing water.

Number of people affected not known: the level of some cells in your blood may change.
You should tell your doctor straight away if you have any of the following symptoms:

- You develop any unexplained bruising or bleeding
- You develop persistent or repeated mouth ulcers, sore throats or other infections.

A few cases have been reported of severe skin reactions after taking sodium fusidate, which may develop into potentially life-threatening skin reactions if they are not treated.
The frequency of these side effects is not known (cannot be estimated from the available data):

- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. See also section 2.
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). See also section 2.
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).
- If you develop a serious rash or another of these skin symptoms, stop taking sodium fusidate and contact your doctor or seek medical attention immediately.

Other possible side effects:

Common (affect less than 1 in 10 people):
Pain or inflammation of the vein where sodium fusidate infusion is given, dizziness, drowsiness.

Uncommon (affect less than 1 in 100 people):
Headache, rash, itchy rash, itching, loss of appetite, feeling tired, weak or unwell.

Number of people affected not known:
Pale stools
Dark urine
Upper right hand side stomach pain.

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. You can also report side effects directly via the Yellow Card Scheme at:www.mhra.gov.uk/yellowcard. or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store sodium fusidate infusion

- Keep this medicine out of the sight and reach of children.

Do not use sodium fusidate infusion after the expiry date which is stated on the carton after EXP. The expiry date is the last day of that month.

- Store in a refrigerator (2ºC - 8ºC).

6. Contents of the pack and other information

What sodium fusidate infusion contains

- The active substance is sodium fusidate. A vial of powder contains 500 mg of sodium fusidate.
- The other ingredients are: citric acid, disodium edetate, disodium hydrogen phosphate and water for injections. (See end of Section 2 for further information on sodium).

What sodium fusidate infusion looks like and contents of the pack
Sodium fusidate infusion comes in packs of 2 vials. One vial contains sodium fusidate (powder) and the other vial the solution for the infusion.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Essential Pharma Ltd, 7 Egham Business
Village, Crabtree Road, Egham, Surrey,
TW20 8RB, UK.

Manufacturer:
FAMAR Health Care Services Madrid S.A.U.
Avda. Leganés, 62,
Alcorcón, 28923 Madrid,
Spain
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PLEASE TEAR ALONG THE PERFORATIONS AND RETAIN THIS PORTION BEFORE GIVING THE REMAINING LEAFLET TO THE PATIENT.

FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

Sodium Fusidate 500 mg for Intravenous Infusion
Sodium Fusidate 500 mg (equivalent to 480 mg fusidic acid) contained in one vial. (The second vial contains buffer solution).

Powder for reconstitution and use as an intravenous infusion.

The vial of 10 ml sterile phosphate-citrate buffer solution (pH 7.4 - 7.6) contains disodium hydrogen phosphate, citric acid, disodium edetate and water for injections. (When reconstituted with powder vial contains 3.16 mmol sodium).

Shelf-life and storage conditions: The sodium fusidate dry powder is stable for 2 years when stored in a refrigerator (2ºC - 8ºC). After the sodium fusidate dry powder is dissolved in the buffer solution provided and added to 500 ml of infusion fluid, the solution should be used immediately.
When the buffer solution is transferred to the powder vial, this vial should be regarded as a unit dose. The required amount of solution should be used once only and any unused portion discarded.

Recommended procedure for reconstitution and administration:
To reconstitute, dissolve the contents of one vial containing 500 mg sodium fusidate powder (equivalent to 480 mg of fusidic acid) in the 10 ml buffer provided.
Precipitation can happen when the buffer is stored at low temperatures, which will appear as black spots. If seen, shake the buffer vial until clear before reconstitution with the powder vial. Only clear reconstituted solution free from particles should be used.
For adults weighing more than 50 kg: Add the 10 ml fusidate/buffer solution to 500 ml of infusion fluid.

For children and adults weighing less than 50 kg: Add the 10 ml fusidate/buffer solution to 500 ml of infusion fluid. Each dose corresponds to 6-7 ml of the resulting solution per kg bodyweight.

The diluted fluid should be infused via a central venous line over 2 hours. If a superficial vein is employed a more prolonged period of at least 6 hours is advisable.
This product should be administered intravenously into a wide bore vein with a good blood flow. Excessive doses may cause venospasm, thrombophlebitis and haemolysis 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 used.

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 and chemically compatible with the following infusion solutions (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)
Dextrose Intravenous Infusion BP 5% (1-2 mg/ml)
Compound Sodium Lactate Intravenous Infusion ("Ringer-Lactate Solution") (1 mg/ml)
Sodium Lactate Intravenous Infusion BP (1 mg/ml)
Sodium Chloride (0.18%) and Dextrose (4%) Intravenous Infusion BP (1 mg/ml)
Potassium Chloride (0.3%) and Dextrose (5%) Intravenous Infusion BP (1 mg/ml).

Sodium fusidate reconstituted at 50 mg/ml in buffer solution is physically incompatible with infusion fluids containing 20% or more of dextrose, lipid infusions and peritoneal 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: Essential Pharma Ltd, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.