PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefuroxime 250mg Powder for Injection
Cefuroxime sodium

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 your 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. WHAT CEFUROXIME INJECTION IS AND WHAT IT IS USED FOR

Your medicine contains the active substance Cefuroxime, which is one of a group of medicines called antibiotics. These are used to kill the bacteria or 'germs' that cause infections.
Your doctor has decided to give you Cefuroxime Injection because you have an infection, or to protect you from infection before an operation.

2. BEFORE YOU ARE GIVEN CEFUROXIME INJECTION

Do not take Cefuroxime Injection:
- If you are allergic (hypersensitive) to cefuroxime or other similar antibiotics (called "cephalosporins")
- If you have had a severe allergic reaction to penicillin or other similar antibiotics (called "beta-lactams")
- If you had an immediate allergic reaction when given penicillin or similar antibiotics.

If you are unsure about any of these, ask your doctor.

Take special care with Cefuroxime Injection if you have been told that your kidneys are not working as well as they should be. Talk to your doctor if this applies to you.

If you have previously had an allergic reaction to penicillin or other similar antibiotics, you should tell your doctor. It may be alright for you to be given this medicine.
If the allergic reaction was severe or immediate, you should not take this medicine.

Taking other medicines:
Tell your doctor if you are taking any of the following medicines as they may interact with Cefuroxime Injection:
- probenecid, which is a medicine used to treat "gout"
- "water tablets" (to help you go to the toilet) such as furosemide
- an aminoglycoside-type antibiotic or any other antibiotics.

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines including medicines obtained without a prescription.

Pregnancy and breast-feeding:
If you are pregnant, likely to become pregnant or are breast-feeding, you must tell your doctor before you are given this medicine.

Driving and using machines
This medicine has no known effects on the ability to drive or use machines.

Important information about some of the ingredients of Cefuroxime Injection:
This medicine contains approximately 2.2 mmol (51mg) of sodium per gram. This should be taken into consideration by patients on a controlled sodium diet.

3. HOW CEFUROXIME INJECTION IS GIVEN

Cefuroxime Injection will usually be given by a doctor or nurse, either directly into a vein or into a muscle. In some cases, it may be added to an intravenous infusion ('drip').

The correct dose will be decided by your doctor and depends on the type of infection and your weight and age.

Adults:
The usual adult dose is 750mg three times a day. The duration of treatment depends on the type of infection. Larger or more frequent doses are sometimes needed for more severe infections.

For example, to treat gonorrhoea the usual dose is 1.5 grams (1.5g) as a single injection or as two separate 750mg injections.
To treat meningitis, the usual adult dose is 3 grams (3g) every 8 hours.

To prevent infections following an operation, the usual dose is 1.5 grams (1.5g) given at the same time as the anaesthetic. After the operation, your doctor or nurse may give you 750mg injections at regular intervals for up to 48 hours depending on the type of operation.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL
The following information is intended for medical or healthcare professionals only.

Instructions for use and handling:

This medicinal product is for single use only. Discard any unused contents.

Intramuscular use
Add 1ml water for injections to Cefuroxime 250mg powder for injection. Shake gently to produce an opaque suspension (final volume 1.1ml).

Intravenous use
Dissolve in water for injections using at least 2ml to produce a clear solution (final volume 2.1ml).

Reconstituted solutions may be diluted with:
10% dextrose
0.9% sodium chloride injection
M/6 sodium lactate injection
Ringer's injection
Lactated Ringer's injection

These solutions may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids.

Storing Cefuroxime Injection:

Keep vials in outer carton to protect from light.
Reconstituted solution: Chemical and physical stability has been demonstrated for 24 hours at 2°C – 8°C and for 8 hours at 25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally be no longer than 24 hours at 2-8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

Incompatibilities

Solutions containing cefuroxime should not be mixed with or added to solutions containing other agents other than those listed opposite.

The pH of 2.74% w/v sodium bicarbonate injection BP considerably affects the colour of solutions and therefore this solution is not recommended for the dilution of cefuroxime powder for injection. However, if required, for patients receiving sodium bicarbonate injection by infusion, the cefuroxime powder for injection may be introduced into the tube of the giving set.

Cefuroxime powder for injection should not be mixed in the syringe with aminoglycoside antibiotics.

Posology and method of administration

Usually cefuroxime is effective when administered alone, but when appropriate it may be used in combination with metronidazole or an aminoglycoside.

General Dosage

Adults: Many infections will respond to 750mg three times daily by intramuscular or intravenous injection. For more severe infections, this dose should be increased to 1.5g three times daily intravenously. The frequency of dosage may be increased to six-hourly injections (intramuscular or intravenous) giving total daily doses of 3g to 6g.

Infants and Children: Doses of 30 to 100mg/kg/day given as three or four divided doses. A dose of 60 mg/kg/day will be appropriate for most infections.

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PRODUCT NAME:
Cefuroxime Villerton 250mg Bowmed UK

PRODUCT CODE:
L08GBCEFU2505

SEPARATIONS:
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PHARMACODE: **I X X I I X X X X**
MEAS. (mm): **210 x 315 (105x52,5)**
CUTTING PROFILE: **ACSI092F00**
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Children:
For infants and children, the dose is based on how much they weigh and is usually between 30mg to 100mg per kilogram daily divided into three or four separate doses. For newborn children the dose is the same as for infants and children, but is divided into 2 or 3 doses.

To treat meningitis, the usual dose is between 200mg to 240mg per kilogram daily divided into three or four separate doses. This may be reduced to 100mg per kilogram daily when your child shows signs of improvement.
For newborn children, the usual dose is 100mg per kilogram daily which may be reduced to 50mg per kilogram daily when your child shows signs of improvement.

Patients with kidney problems:
For patients with kidney problems, the usual dose is 750mg given once or twice daily.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefuroxime Injection can cause side effects, although not everybody gets them.

As with other antibiotics, some people find they have an allergy to it. Tell your doctor immediately if any of the following symptoms occur:
- **Sudden wheeziness and tightness of chest**
- **Swelling of eyelids, face or lips**
- **Skin lumps or "hives" (nettle rash)**
- **Severe skin rashes with itching**

Antibiotic treatment can affect the normal bacteria in the gut, causing new infection (colitis). You should tell your doctor **immediately** if you develop diarrhoea.

The following side effects may occur in some patients treated with Cefuroxime injection. Tell your doctor if any become troublesome:

Common side effects (probably affecting more than 1 in 100 patients)
- Reduction in number of white blood cells which makes infections more likely
- Increase in number of white blood cells
- Increased liver enzymes
- Pain, redness and swelling at the injection site

Uncommon side effects (probably affecting less than 1 in 100 patients)
- Reduced haemoglobin concentration
- False positive blood tests
- Rash with small, raised, red areas of skin (which may be itchy and/or scaly)
- Itching
- Loose stools or diarrhoea
- Skin and whites of the eyes turn yellow

Rare side effects (probably affecting less than 1 in 1,000 patients)
- Fewer red blood cells which can make the skin pale and cause weakness or breathlessness
- Reduction in blood platelets which increases risk of bruising or bleeding
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Fever
- Yeast infections e.g. thrush

Very rare side effects (probably affecting less than 1 in 10,000 patients)
- Reduction in red blood cells which can make the skin pale or yellow and cause weakness or breathlessness
- Diarrhoea containing blood (which may be a sign of a condition called pseudomembranous colitis)
- Problems with kidney function
- Serious illness with blistering of the skin, mouth, eyes and genitals

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

5. HOW TO STORE CEFUROXIME INJECTION

Keep out of the reach and sight of children.
Do not use Cefuroxime Injection after the expiry date which is printed on the label and carton.
Keep vials in outer carton to protect from light.
Your doctor, pharmacist or nurse will know how to store Cefuroxime Injection properly.

6. FURTHER INFORMATION

What Cefuroxime Injection contains
- The active substance is Cefuroxime 250mg
- Your medicine contains no other ingredients

What Cefuroxime Injection looks like and contents of the pack:
Cefuroxime Injection is a white powder in a glass vial.
Each vial contains 250mg of Cefuroxime.
Each carton contains 1, 5, 10, 20 or 50 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
VILLERTON INVEST SA
Rue Edward Steichen 14
2540 Luxembourg

Manufacturer:
Facta Farmaceutici SpA, 64100 Teramo, Italy

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Neonates: Doses of 30 to 100mg/kg/day given as two of three divided doses. In the first weeks of life the serum half-life of cefuroxime can be three to five times that in adults.

Elderly: See dosage in adults

Gonorrhoea:
1.5g should be given as a single dose or as two 750mg injections into different sites e.g. each buttock.

Meningitis:
Cefuroxime powder for injection is suitable for sole therapy of bacterial meningitis due to sensitive strains. The following dosages are recommended.

Infants and children: 200 to 240mg/kg/day intravenously in three or four divided doses. This dosage may be reduced to 100mg/kg/day after three days or when clinical improvement occurs.

Neonates: The initial dose should be 100mg/kg/day intravenously. This may be reduced to 50mg/kg/day when clinically indicated.

Adults: 3g intravenously every eight hours. No data are currently available to recommend a dose for intrathecal administration.

Prophylaxis:

The usual dose is 1.5g intravenously with induction of anaesthesia. For abdominal, pelvic and orthopaedic operations this may be followed with two 750mg doses 8 and 16 hours later. For cardiac pulmonary, oesophageal and vascular operations, this may be supplemented with 750mg intramuscularly three times a day for a further 24 to 48 hours.

In total joint replacement, 1.5g cefuroxime powder may be mixed dry with each pack of methyl methacrylate cement polymer before adding the liquid monomer.

Dosage in impaired renal function

As cefuroxime is excreted by the kidneys, the dosage should be reduced to allow for slower excretion in patients with impaired renal function, once creatinine clearance falls below 20ml/min, as follows:

Marked impairment (creatinine clearance 10 – 20ml/min): 750mg twice daily.
Severe impairment (creatinine clearance <10ml/min): 750mg once daily.
For patients on haemodialysis, a further 750mg dose should be given at the end of each dialysis.
Continuous peritoneal dialysis: 750mg twice daily.
Renal failure on continuous arteriovenous haemodialysis or high-flux haemofiltration in intensive therapy units: 750mg twice daily.
Low-flux haemofiltration: as for impaired renal function.

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