PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefuroxime Actavis 250 mg powder for solution for injection
Cefuroxime Actavis 750 mg powder for solution for injection
Cefuroxime Actavis 1.5 g powder for solution for injection or infusion

Cefuroxime

Read all of this leaflet carefully before you start receiving this medicine.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

Cefuroxime belongs to a group of antibiotics called cephalosporins.
Antibiotics are used to kill the bacteria or 'germs' that cause infections.

Cefuroxime is a powder which is made into a solution to be given by injection into a vein or into a muscle.

Cefuroxime Actavis is given for the treatment of infections including infections of the chest and kidneys.

A doctor may also give it to you before an operation to protect you from infection.

2. BEFORE YOU ARE GIVEN CEFUROXIME ACTAVIS

Do not use Cefuroxime Actavis:
- if you are allergic (hypersensitive) to cefuroxime (see section 6 for a list of the ingredients).
- if you have had an allergic reaction to antibiotics such as penicillin or cephalosporins (an allergic reaction may include a rash, itching or breathing difficulties).

Take special care with Cefuroxime Actavis:
- if you have kidney disease or if you are on dialysis.
- if you have liver problems.
- if you have any blood tests, Cefuroxime Actavis can cause changes to the results.

Long time use of Cefuroxime Actavis can result in infections caused by organisms that are not sensitive to Cefuroxime Actavis.

Diarrhoea may develop while you are on antibiotics, including Cefuroxime Actavis, or even several weeks after you have stopped using them. If it becomes severe or persistent or you notice that your

stool contains blood or mucus tell your doctor immediately. Cefuroxime Actavis treatment will have to be stopped immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.

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

The doctor will take special care if you are using any of the following medicines at the same time:
- Diuretics (water tablets), e.g. furosemide
- Probenecid (used to treat gout)
- Other antibiotics (e.g. amphotericin, aminoglycosides, tetracyclines, macrolides or chloramphenicol)

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

There is no evidence of harmful effects caused by Cefuroxime Actavis in pregnancy. But, Cefuroxime Actavis should only be given during pregnancy after careful consideration of the risks and benefits. If you are pregnant or think you may be pregnant or you are trying to become pregnant, tell you doctor or pharmacist before taking this medicine.

Cefuroxime Actavis is excreted in breast milk and should be given with care to breast-feeding mothers. Please tell you doctor if you are breast-feeding.

Driving and using machines
In rare cases Cefuroxime Actavis may cause dizziness, nervousness or confusion. If you feel at all unwell after being given Cefuroxime Actavis you should not attempt to drive or use machines.

Important information about some of the ingredients of Cefuroxime Actavis
50 mg vial This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially 'sodium- free'.

For 750 mg vial This medicinal product contains 1.8 mmol (42 mg) sodium per vial. To be taken into consideration by patients on a controlled sodium diet

For 1500 mg vial This medicinal product contains 3.7 mmol (84 mg) sodium per vial. To be taken into consideration by patients on a controlled sodium diet

3. HOW CEFUROXIME ACTAVIS IS GIVEN

Your doctor will decide on the dose and the duration of treatment. This medicine will normally be given by an injection of a solution into a vein or a muscle. The usual dose is:

Adolescents (aged 12 years to 17 years), adults and elderly:
750 mg to 1500 mg three times a day. For more severe infections this may be increased to 750 mg to 1500 mg four times a day.

Your doctor may give you 1500 mg Cefuroxime Actavis before surgery to protect you from infection. You may get further doses of 750 mg of cefuroxime after the operation.

Infants (aged 28 days to 23 months) and children (2 years to 11 years): The dose is based on body weight and is normally between 30 mg to 100 mg (usually 60 mg) for each kilogram of their body weight each day. This will be divided into doses of three or four times a day.

Patients with kidney disorders

If you have kidney problems, you may be given a lower dose just once or twice a day depending on your kidney function.

If you miss a dose or receive too much of Cefuroxime Actavis
As this medicine will be given to you whilst you are in hospital, it is unlikely that you will miss a dose or be given too much however, if you have any concerns discuss this with your doctor or nurse.

While you are receiving Cefuroxime Actavis
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefuroxime Actavis can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

If you notice any of the following serious side effects, stop taking Cefuroxime Actavis and contact a doctor immediately:
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be "Stevens-Johnson syndrome" or "toxic epidermal necrolysis".
- Severe prolonged diarrhoea, which may have blood or mucus in it, accompanied with stomach pain and fever. This could be "pseudomembranous colitis".

These effects are rare, affecting less than 1 in 1,000 people.

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction).
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems (jaundice).

These effects are very rare, affecting less than 1 in 10,000 people.

Other side effects include:

Common side effects (affects 1 to 10 users in 100):
- Diarrhoea, nausea or vomiting.
- Skin rash, itchy skin.
- Increase in some substances in you blood (creatinine and urea) especially in patients with kidney problems.
- Pain or swelling where the needle went into the vein or muscle.

Uncommon side effects (affects 1 to 10 users in 1,000):
- Abnormal increase in a certain type of white blood cells in your blood (eosinophilia). Symptoms include weight loss, night sweats and fever.
- Abnormal decrease in some types of white blood cells in your blood (leucopenia and neutropenia), which can make you more likely to get infections.
- Unusual bleeding or bruising caused by a reduction in the number of platelets in the blood (thrombocytopenia).
- Headache, dizziness.
- Severe kidney problems (especially in elderly patients and patients with previous kidney disorders).
- Changes to test used to measure functioning of the liver.

Rare side effects (affects 1 to 10 users in 10,000)
- Abnormal decrease in a certain type of white blood cells in you blood (agranulocytosis) which which can make you more likely to get infections.
- Abnormal decrease of haemoglobin in your blood (anaemia). Symptoms include tiredness, paleness, weakness, dizziness, shortness of breath and fast heart beat.

- Various skin eruptions or rashes (e.g. the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Fever.
- Delayed allergic reaction (serum sickness) where symptoms may include fever, hives, skin rash, joint pains, enlarged glands, shortness of breath and generally feeling unwell. Symptoms can take 1–2 weeks to appear after the start of treatment.
- White furry, sore tongue and mouth (oral thrush).
- Sore, itchy vagina and/or discharge (vaginal thrush).

Very rare side effects (affects less than 1 user in 10,000)
- Abnormal breakdown of red blood cells (haemolytic anaemia). Symtoms include tiredness, paleness, yellowing of skin, weakness, dizziness, shortness of breath and fast heart beat.
- Vertigo (feeling of dizziness or spinning), restlessness, nervousness, confusion.

Not known: frequency cannot be estimated from the available data:
- Some blood tests may become false positive (e.g Combs test).
- Severe allergic reaction (angio-oedema) with swelling of the face (e.g. lips and eyelids), tongue, hands and feet and difficulty breathing.

Reporting of suspected adverse reactions
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CEFUROXIME ACTAVIS

Keep out of the sight and reach of children.

This medicine does not require any special storage conditions.

Reconstituted/diluted solution should be used immediately.
From the microbiological point of view, the product should be used immediately.
If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless reconstitution/dilution has taken place in controlled and validated conditions.

Do not use Cefuroxime Actavis after the expiry date which is stated on the carton.

For single use only.
Discard any unused solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cefuroxime Actavis contains

- The active ingredient is cefuroxime 250 mg or 750 mg or 1500 mg (as sodium salt).
- Other ingredients: None.

What Cefuroxime Actavis looks like and contents of the pack

Cefuroxime is white to faintly yellow powder to which appropriate amounts of water are added to prepare an off-white to pale yellow opaque suspension for intramuscular use or a yellowish solution for intraveneous administration.

250 mg, 750 mg powder for solution for injection:
20 ml type I glass vials, sealed with grey bromo butyl rubber stopper and coloured flip off seal.

1.5 g powder for solution for injection or infusion:
20 ml type I glass vials (for injection) and 100 ml type I glass vials (for infusion), sealed with grey bromo butyl rubber stopper and coloured flip off seal.

Pack sizes:
250 mg powder for solution for injection:
1 vial, 5 vials, 10 vials

750 mg powder for solution for injection:
1 vial, 5 vials, 10 vials

1.5 g powder for solution for injection or infusion:
20 ml vials (injection): 1 vial, 5 vials, 10 vials
100 ml vials (infusion): 1 vial, 5 vials, 10 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

Manufacturer

Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

This medicinal product is authorised in the Member States of the EEA under the following names:

UK:	Cefuroxime 250mg powder for solution for injection
	Cefuroxime 750mg powder for solution for injection
	Cefuroxime 1.5g powder for solution for injection/ infusion
IE:	Cefuroxime Actavis 250mg powder for solution for injection
	Cefuroxime Actavis 750mg powder for solution for injection
	Cefuroxime Actavis 1.5 g powder for solution for injection or infusion

This leaflet was last approved in February 2016.

The following information is intended for medical or healthcare professionals only:

For single use only. Discard any unused solution.

The dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Preparation of solution

Intramuscular
Add 1 ml water for injections to 250 mg Cefuroxime Actavis or 3 ml water for injections to 750 mg Cefuroxime Actavis. Shake gently to produce an opaque suspension.

Intravenous
Dissolve Cefuroxime Actavis in water for injections using 2 ml for 250 mg, 6 ml for 750 mg or 15 ml for 1500 mg (1.5 g). For short intravenous infusion (e.g. up to 30 minutes), 1500 mg (1.5 g) may be dissolved in 50 ml water for injections. 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. The reconstituted solution should appear yellowish.

Cefuroxime is compatible with most commonly used intravenous fluids and electrolyte solutions. Water for injections is recommended for reconstitution, followed by dilution (prior to intravenous administration) with water for injections, 5% glucose injection or 0.9% sodium chloride injection. Cefuroxime Actavis is also compatible with Hartmann's solution and 0.18% sodium chloride + 4% glucose.

Reconstituted product:
Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C to 8°C.