Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user Ceftaroline Fosamil Powder for Concentrate for Solution for Infusion ZINFORO®

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Zinforo (Ceftaroline fosamil) is and what it is used for
2. What you need to know before you take Zinforo (Ceftaroline fosamil)
3. How to take Zinforo (Ceftaroline fosamil)
4. Possible side effects
5. How to store Zinforo (Ceftaroline fosamil)
6. Contents of the pack and other information

1. What Zinforo (Ceftaroline fosamil) is and what it is used for

What Zinforo (Ceftaroline fosamil) is

Zinforo (Ceftaroline fosamil) is an antibiotic medicine that contains the active substance ceftaroline fosamil. It belongs to a group of medicines called 'cephalosporin antibiotics.'

What Zinforo (Ceftaroline fosamil) is used for

Zinforo (Ceftaroline fosamil) is used to treat adults (≥18 years of age) with:

- An infection of the lungs called 'pneumonia' (specifically Community-acquired pneumonia)
- Complicated skin and soft tissue infections (cSSTI) i.e. infections of the skin and the tissues below the skin

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How Zinforo (Ceftaroline fosamil) works

Zinforo (Ceftaroline fosamil) works by killing certain bacteria, which can cause serious infections.

2. What you need to know before you take Zinforo (Ceftaroline fosamil)

Do not take Zinforo (Ceftaroline fosamil)

- If you are allergic to ceftaroline fosamil or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other cephalosporin antibiotics.
- If you have had previous severe allergic reactions to other antibiotics like penicillin or beta lactam.

Do not use Zinforo (Ceftaroline fosamil) if any of the above applies to you. If you are not sure, talk to your doctor or nurse before using Zinforo (Ceftaroline fosamil).

Warnings and precautions

Talk to your doctor or nurse before using Zinforo (Ceftaroline fosamil):

- If you have kidney problems (your doctor may have to prescribe a lower dose)
- If you have ever had fits (seizures or convulsions)
- If you have ever had any non-severe allergic reactions to other antibiotics like penicillin or carbapenem
- If you have had severe diarrhoea whilst taking antibiotics in the past

You may get another infection caused by another bacteria during or following treatment with Zinforo (Ceftaroline fosamil).

You may develop signs and symptoms of severe skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Lab Test

You may develop an abnormal lab test (called Coombs test) that looks for certain antibodies which may act against your red blood cells. If the level of your red blood cells fall your doctor may check to see if these antibodies have caused this.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before using Zinforo (Ceftaroline fosamil).

Other medicines and Zinforo (Ceftaroline fosamil)

No clinical drug-drug interaction studies have been conducted with Zinforo (ceftaroline fosamil).

Pregnancy and breast-feeding

Tell your doctor before using Zinforo (Ceftaroline fosamil) if you are pregnant. Do not use this medicine during pregnancy unless your doctor has told you to.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Zinforo (Ceftaroline fosamil) may cause side effects such as dizziness. This may impair your ability to drive or use machines.

3. How to take Zinforo (Ceftaroline fosamil)

Zinforo (Ceftaroline fosamil) will be given to you by a doctor or nurse.

How much to use

The usual recommended dose for adults is 600 mg every 12 hours. Your doctor may increase your dose to 600 mg every 8 hours for some infections. It is given as a drip into a vein lasting 5 to 60 minutes if you receive the usual dose or 120 minutes if you receive an increased dose.

A course of treatment usually lasts for 5 to 14 days for skin infections and 5 to 7 days for pneumonia.

Patients with kidney problems

If you have kidney problems your doctor may lower your dose because Zinforo (Ceftaroline fosamil) is removed from your body by the kidneys.

If you use more Zinforo than you should

If you think you have been given too much Zinforo (Ceftaroline fosamil), tell your doctor or nurse straight away.

If you miss a dose of Zinforo (Ceftaroline fosamil)

If you think you have missed a dose, tell your doctor or nurse straight away.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Tell your doctor straight away if you get these symptoms as you may need urgent medical treatment:

- Severe skin reactions (not known, frequency cannot be estimated from the available data)
    - Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- Sudden swelling of your lips, face, throat or tongue; a severe rash; and, swallowing or breathing problems. These may be signs of a severe allergic reaction (anaphylaxis) and may be life-threatening;
- Diarrhoea that becomes severe or does not go away or stool that contains blood or mucus during or after treatment with Zinforo (Ceftaroline fosamil). In this situation, you should not take medicines that stop or slow bowel movement.

Very common (may affect more than 1 in 10 people)

- Changes in a blood test called a 'Coombs test' commonly seen in patients receiving this type of antibiotic. This test looks for certain antibodies which may act against your red blood cells.

Common (may affect up to 1 in 10 people)

- Fever
- Headache
- Feeling dizzy
- Itching, skin rash
- Diarrhoea, stomach pain
- Feeling sick (nausea) or being sick (vomiting)
- More enzymes produced by your liver (as shown in blood tests)
- Pain and irritation of the veins
- Redness, pain or swelling where the injection was given.

Uncommon (may affect up to 1 in 100 people)

- Anaemia
- Raised itchy rash (hives)
- *Clostridium difficile* colitis
- An increase in the level of creatinine in your blood. Creatinine shows how well your kidneys are working.
- Bleeding or bruising more than usual. This may be because the level of platelets in your blood has dropped.
- Changes in tests which measure how well your blood clots.
- A decrease in the total number of white blood cells, or a certain type of white blood cells in your blood (leucopenia and neutropenia).
- Changes in your mental state such as confusion, reduced level of consciousness, abnormal movements or fits (encephalopathy) – these have occurred in people when the dose they are given is too high, particularly in people with kidney problems.

Rare (may affect up to 1 in 1,000 people)

- A significant decrease in the number of certain white blood cells in your blood (agranulocytosis). You may experience fever, flu-like symptoms, sore throat, or any other infection which may be serious.

- An increase in the number of certain white blood cells in your blood (eosinophilia).

Not known (frequency cannot be estimated from the available data)

- A form of lung disease where eosinophils (a form of white blood cell) appear in the lung in increased numbers (eosinophilic pneumonia).

Sudden chest pain, which may be a sign of a potentially serious allergic reaction called Kounis syndrome has been noted with other medicines of the same type. If this happens talk to a doctor or nurse immediately.

Reporting of side effects

If you experience any side effects, contact your doctor immediately. This also applies to side effects not specified in this leaflet

5. How to store Zinforo (Ceftaroline fosamil)

Store in a dry, well-ventilated place at a temperature not exceeding 30°C.

Store in the original package in order to protect from light.

Each vial is for single use only.

6. Contents of the pack and other information

What Zinforo (Ceftaroline fosamil) contains

Each vial contains ceftaroline fosamil acetic acid solvate monohydrate equivalent to ceftaroline fosamil 600 mg.

The other ingredient is L-arginine.

What Zinforo (Ceftaroline fosamil) looks like and contents of the pack

Zinforo (Ceftaroline fosamil) is a pale yellowish- white to light yellow sterile powder for concentrate for solution for infusion in a vial.

20 mL glass vial (Type 1) closed with a rubber (halobutyl) stopper and aluminium seal with flip-off cap.

It is available in packs containing 10 vials.

DETAILS OF MANUFACTURER

Manufactured By

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Marketed in India by

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