Package leaflet: Information for the user
Zinforo ® 600 mg powder for concentrate for solution for infusion
Ceftaroline fosamil

Read all of this leaflet carefully before you start using 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 nurse.
- 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 is and what it is used for

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

What Zinforo is used for
Zinforo is used to treat children (from birth) and adults with:
- infections of the skin and the tissues below the skin
- an infection of the lungs called 'pneumonia'

How Zinforo works
Zinforo works by killing certain bacteria, which can cause serious infections.

2. What you need to know before you use Zinforo

Do not use Zinforo:
- 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 carbapenem.

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

Warnings and precautions
Talk to your doctor or nurse before using Zinforo:
- 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.

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.

Other medicines and Zinforo
Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
Tell your doctor before using Zinforo 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 may cause side effects such as dizziness. This may impair your ability to drive or operate machinery.

3. How to use Zinforo

Zinforo 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. The usual recommended dose for children depends on the age and weight of the child and is given every 8 or 12 hours. 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 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, tell your doctor or nurse straight away.

If you miss a dose of Zinforo
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 or nurse.

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:

- 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. 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)
- 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).

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).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland HPRA

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Zinforo

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

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Store below 30°C.

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

Medicines should not be disposed of via wastewater or household waste. The hospital will dispose of any waste materials safely. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zinforo contains
- Each vial contains 600 mg of ceftaroline fosamil.
- The other ingredient is arginine.

What Zinforo looks like and contents of the pack
Zinforo is a pale yellowish-white to light yellow powder for concentrate for solution for infusion in a vial. It is available in packs containing 10 vials.

Marketing Authorisation Holder

Pfizer Ireland Pharmaceuticals
Operations Support Group
Ringaskiddy, County Cork
Ireland

Manufacturer

ACS Dobfar S.p.A.
Nucleo Industriale S. Atto
64100 Teramo
Italy

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This leaflet was last revised in 07/2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Ref: ZI 8_0

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

Important: Please refer to the Summary of Product Characteristics before prescribing.

Aseptic technique must be followed in preparing the infusion solution. The contents of Zinforo vial should be reconstituted with 20 mL of sterile water for injections. Instructions for the reconstitution of Zinforo vial are summarized below:

Dosage strength (mg)	Volume of diluent to be added (mL)	Approximate ceftaroline concentration (mg/mL)	Amount to be withdrawn
600	20	30	Total volume

The reconstituted solution must be further diluted to produce Zinforo solution for infusion. A 250 mL, 100 mL or 50 mL infusion bag can be used to prepare the infusion, based on the patient's volume requirements. Appropriate infusion diluents include: sodium chloride 9 mg/mL (0.9%) solution for injection, dextrose 50 mg/mL (5%) solution for injection, sodium chloride 4.5 mg/mL and dextrose 25 mg/mL solution for injection (0.45% sodium chloride and 2.5% dextrose) or Lactated Ringer's solution. The resulting solution should be administered according to the dose selected over 5 to 60 minutes for standard dose or 120 minutes for high dose in infusion volumes of 50 mL, 100 mL or 250 mL.

Infusion volumes for paediatric patients will vary according to the weight of the child. The infusion solution concentration during preparation and administration should not exceed 12 mg/mL ceftaroline fosamil.

Reconstitution time is less than 2 minutes. Mix gently to reconstitute and check to see that the contents have dissolved completely. Parenteral drug products should be inspected visually for particulate matter prior to administration.

The colour of Zinforo infusion solutions ranges from clear, light to dark yellow depending on the concentration and storage conditions. It is free of any particles. When stored as recommended, the product potency is not affected.

Studies have shown that Zinforo solutions for infusion are stable for up to 6 hours at room temperature. Alternatively, they are stable for up to 24 hours under refrigerated storage. Once removed from refrigeration to room temperature, the diluted product must be used within 6 hours.

From a microbiological point of view, the medicinal product should be used immediately unless reconstitution and dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

The compatibility of Zinforo with other medicines has not been established. Zinforo should not be mixed with or physically added to solutions containing other drugs.

Each vial is for single use only.

Any unused product or waste material should be disposed of in accordance with local requirements.