

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about Zinforo. It does not contain all the available information. It does not take the place of talking to your/your child's doctor, nurse or pharmacist.

All medicines have risks and benefits. Your/your child's doctor will have weighed the risks of taking Zinforo against the benefits they expect it will have for you/your child.

If you/your child have any concerns about taking this medicine, ask the doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Zinforo is used for

Zinforo is an antibiotic used to treat serious infections caused by bacteria (germs), such as:

- infections of the skin and tissue below the skin
- infection of the lungs (pneumonia).

Zinforo will not work against fungal or viral infections (such as colds or the flu).

Zinforo belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing the infection.

Zinforo is given by injection and is mostly given in hospital. Some

patients may also be given Zinforo in "hospital in the home". It is available only with a doctor's prescription.

Ask your/your child's doctor if you/your child have any questions about why this medicine has been prescribed.

The doctor may have prescribed it for another reason.

This medicine is not addictive.

The side effects of this medicine may affect the ability to drive a car or operate machinery.

Before Zinforo is given

When you/your child must not be given it

Do not take Zinforo if you have/your child has an allergy to:

- any medicine containing ceftaroline, the active ingredient in Zinforo
- L-arginine (inactive ingredient in Zinforo)
- other cephalosporin antibiotics.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Zinforo if you have/your child has had a serious allergy to penicillins or beta-lactam antibiotics (e.g., carbapenems).

You/your child may be more likely to have an allergic reaction to Zinforo if you/your child have had an allergic reaction to these other antibiotics.

The hospital staff will check that the expiry date printed on the pack has not passed and that the packaging is not torn or showing signs of tampering.

If you are not sure whether you/your child should be given this medicine, talk to the doctor, pharmacist or nurse.

Before you/your child are given it

Tell the doctor or nurse if you/your child have any type of allergic reaction to penicillin or beta-lactam antibiotics (e.g., carbapenems).

You/your child may be more likely to have an allergic reaction to Zinforo if you/your child are allergic to these other antibiotics.

Tell the doctor or nurse if you/your child have allergies to any other medicines, foods, preservatives or dyes.

Tell the doctor or nurse if you/your child have or have had any of the following medical conditions:

- kidney problems
- fits (seizures/convulsions)
- severe diarrhoea after taking any antibiotics.

Tell the doctor if you or your child are pregnant or plan to become pregnant or are breast-feeding.

The doctor can discuss with you/your child the risks and benefits involved.

If you/your child have not told the doctor about any of the above, tell

him/her before you/your child are given Zinforo.

Taking other medicines

Tell the doctor, nurse or pharmacist if you/your child are taking any other medicines, including any that you get without a prescription from the pharmacy, supermarket or health food shop.

The doctor, nurse and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Zinforo is given

Zinforo treatment is mostly given in hospital. Some patients may also be given Zinforo in "hospital in the home". It is given as a slow injection (infusion) directly into a vein, which usually takes 60 minutes.

It must only be given by a doctor or nurse.

How much will be given

The doctor will decide what dose of Zinforo you/your child will need depending on certain factors such as the type of infection, age and bodyweight (for children) and if you/your child have kidney problems.

Adults (18 years and over):

The usual adult dose is 600 mg every 12 hours.

Children (2 months to 17 years):

The dose in children varies depending on body weight, and is given every 8 hours. Older children (12 to 17 years) over a certain body weight may be given the adult dose (every 12 hours). Your child's doctor will decide what dose needs to be given.

People with kidney problems

If you/your child (from 24 months of age) have kidney problems, the doctor may lower the dose depending on the severity of your/your child's kidney problems.

How long will Zinforo need to be given

Zinforo needs to be given as a series of slow injections (infusions) over a few days. The doctor will decide how many days you/your child will need to be given Zinforo.

Ask the doctor, nurse or pharmacist if you have any questions including how this medicine is prepared, how it will be given to you/your child or how long it will need to be given.

If you/your child have missed a dose

If you are concerned that a dose of Zinforo may have missed, tell the doctor or nurse straight away.

If too much has been given (overdose)

As Zinforo is given under the close supervision of the doctor or nurse, it is unlikely that you/your child will be given too much. If you are concerned that too much has been given, tell the doctor, nurse or pharmacist immediately.

While using Zinforo

Things you/your child must do

If the symptoms of the infection do not improve within a few days, or if they become worse, tell the doctor.

If you/your child get severe diarrhoea tell the doctor, pharmacist or nurse immediately. Do this even if it occurs several

weeks after Zinforo has been stopped.

Diarrhoea may mean that there is a serious condition affecting the bowel. You/your child may need urgent medical care. Do not take/give your child any diarrhoea medicine without first checking with the doctor.

If any new medicines are about to be started remind the doctor, nurse and pharmacist that you are/your child is taking Zinforo.

Tell any other doctors (including surgeons and anaesthetists), dentists, nurses and pharmacists who treat you/your child that you/your child are being treated with this medicine.

If you/your child find out you/your child are pregnant while taking this medicine, tell the doctor immediately.

If you/your child are about to have any blood tests, tell the doctor or nurse that you are/your child is taking this medicine.

Side effects

Tell the doctor, nurse or pharmacist as soon as possible if you/your child do not feel well while taking Zinforo.

This medicine helps most people with serious infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You/your child may need medical attention if you/your child get some of the side effects.

Do not be alarmed by the following lists of side effects. You/your child may not experience any of them.

Ask the doctor, nurse or pharmacist to answer any questions you may have.

Tell the doctor, nurse or pharmacist if you/your child notice any of the following and they worry you/your child:

- diarrhoea (mild – see next section if severe diarrhoea or if it doesn't go away), stomach pain
- headache
- feeling sick (nausea) or being sick (vomiting)
- itching, skin rash
- feeling dizzy
- fever.

The above list includes the more common side effects this medicine. They are usually mild and short-lived.

Other side effects (e.g., redness, pain and swelling) may occur where the injection was given.

If any of the following happen, tell the doctor or nurse immediately, or if not in hospital already go to Accident and Emergency at your nearest hospital:

- sudden swelling of the lips, face, throat or tongue, a severe rash, 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 stools that contain blood or mucus.

Do not take any diarrhoea medicine without checking with the doctor.

- severe skin reaction such as painful red areas, large blisters, peeling of your skin, and bleeding in the lips, eyes, mouth, nose and genitals.

Your doctor may need to stop your treatment with Zinforo and change to another antibiotic if this occurs.

- sudden fever, chills, weakness in your limbs, sore throat, mouth or gums including mouth ulcers or bleeding gums. These may be signs of a condition which affects certain white blood cells that help to fight infections

The above list includes very serious side effects. You/your child may

need urgent medical attention or hospitalisation.

Occasionally, Zinforo may be associated with changes in the blood, such as an increase in some white blood cells that may require the doctor or nurse to do certain blood tests.

Tell the doctor, nurse or pharmacist if you/your child notice anything that is making you/your child feel unwell.

Other side effects not listed above may also occur in some people.

After finishing Zinforo

Tell the doctor immediately if you/your child notice watery or severe diarrhoea (which may also contain blood or mucus), particularly if it occurs several weeks after stopping treatment with Zinforo.

You/your child may have a serious condition affecting the bowel which may need urgent medical attention.

Do not take/give your child any diarrhoea medicine without first checking with the doctor.

Storage

The hospital and/or pharmacy staff will store Zinforo vials in a safe place at a temperature below 25°C and away from light. They will also prepare and store the infusion bags/bottles ready for the injection.

Product description

What it looks like

Zinforo vials contain a pale yellowish-white to light yellow powder. The hospital and/or pharmacy staff dissolves the powder in water for injection, then transfer to an infusion bag/bottle containing certain solutions (e.g., normal saline) ready for the injection.

Ask the doctor, nurse or pharmacist if you/your child have any questions about how they prepare the injection.

Ingredients

Zinforo contains 600 mg of ceftaroline fosamil as the active ingredient.

It also contains L-arginine (an amino acid) as the inactive ingredient.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

www.pfizer.com.au.

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