Zinforo®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with Zinforo?

Zinforo contains the active ingredient, ceftaroline fosamil. Zinforo is used to treat you or your child for serious infections of the skin, tissues under the skin and infection of the lungs (pneumonia).

For more information, see Section <u>1. Why am I being</u> <u>treated with Zinforo?</u> in the full CMI.

2. What should I know before treatment with Zinforo?

Do not start treatment if you/your child have ever had an allergic reaction to Zinforo/ceftaroline, other antibiotics that are the same type, or any of the ingredients listed at the end of the CMI including L-arginine.

Tell the doctor if you/your child have had any allergic reaction to any antibiotic; have other medical conditions; take any other medicines; or if you are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before treatment with Zinforo?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zinforo and affect how it works.

More instructions can be found in in Section <u>3. What if I</u> <u>am taking other medicines?</u> in the full CMI.

4. How is Zinforo given?

The doctor will decide how much Zinforo is needed. It will depend on factors such as the type of infection, age and bodyweight (for children) and if you have kidney problems.

More instructions can be found in Section <u>4. How is</u> <u>Zinforo given?</u> in the full CMI.

5. What should I know during treatment with Zinforo?

Things you should do	 Tell your doctor if you/ your child have kidney
	problems; have suffered

	 from fits (seizures/ convulsions); had severe diarrhoea after taking any antibiotics; or if you are pregnant, plan to become pregnant or are breastfeeding. For more information on "Things you should do" can be found in Section 6 in the full CMI.
Things you should not do	 You should not be treated with Zinforo if you/your child have had a serious allergy to penicillin or the same type of antibiotics as Zinforo. Your doctor will know which antibiotics are the same type as Zinforo.
Driving or using machines	 Zinforo may affect your ability to drive a car or operate machinery.
Looking after your medicine	 Store in original carton at below 25°C until ready for use.

For more information, see Section <u>5. What should I know</u> <u>during treatment with Zinforo?</u> in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include sudden swelling of the lips, face, throat or tongue (allergic reactions); stomach pain; nausea or vomiting; constipation; itching: skin rash; painful red areas, large blisters, peeling of your skin and bleeding in the lips, eyes, mouth, nose or genitals; dizziness; trouble sleeping; pain and irritation at the injection site and vein; problems with muscles; severe diarrhoea or stools that contain blood or mucus; fever, headache, chills, weakness in your limbs, sore throat, mouth or problems with your gums; bleeding or bruising more than usual; confusion and personality changes; pneumonia; problems with your liver or kidneys, certain blood cells or the way your blood clots.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

ZINFORO®

ceftaroline fosamil

Consumer Medicine Information (CMI)

This leaflet provides important information about Zinforo. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Zinforo.

Where to find information in this leaflet:

- 1. Why am I being treated with Zinforo?
- 2. What should I know before treatment with Zinforo?
- 3. What if I am taking other medicines?
- 4. How is Zinforo given to you?
- 5. What should I know while being treated with Zinforo?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with Zinforo?

Zinforo contains the active ingredient ceftaroline fosamil. Zinforo is an antibiotic used to treat serious infections of the skin, tissues below the skin and infection of the lungs (pneumonia).

2. What should I know before treatment with Zinforo?

Warnings

Do not use Zinforo if you/your child are:

- allergic to Zinforo/ceftaroline or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- allergic to or have previously had a severe allergic reaction to penicillin or the same type of antibiotic as Zinforo. Your doctor will know which antibiotics are the same type as Zinforo.

Check with your doctor if you/your child:

- have kidney problems
- have ever suffered from fits (seizures/convulsions)
- have had severe diarrhoea after taking any antibiotics.
- are taking medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Zinforo.

4. How is Zinforo given?

How much will be given

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

How long will Zinforo need to be given?

A course of treatment usually lasts for 5 to 14 days for skin infections and 5 to 7 days for pneumonia. The doctor will decide how many days you will need treatment with Zinforo.

If too much Zinforo is given

If you think that you/your child have been given too much Zinforo, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with Zinforo?

Things you should do

If you/your child are about to have any blood tests, tell the doctor or nurse that you/your child were recently treated with Zinforo.

Call your doctor straight away if you/your child:

 get severe diarrhoea. Do this even if it occurs several weeks after Zinforo has been stopped.

Remind any doctor, nurse, dentist or pharmacist you see that you are using Zinforo.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Zinforo affects you.

Zinforo may affect your ability to drive a car or operate machinery.

Drinking alcohol

No information available.

Looking after your medicine

Zinforo should be stored in the original carton below 25°C.

If you are keeping this medicine at home, store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it in the bathroom, near a sink or in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any medicine that has passed the expiry date.

This medicine should only be used on one patient and any unused medicine should be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them will be minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Side effects	What to do
 Stomach pain Nausea or vomiting Constipation Itching Skin rash Dizziness Trouble sleeping Fever Headache Redness, pain or swelling where the injection was given and 	Speak to your doctor or nurse if you have any of these side effects and they worry you.

Side effects	What to do
 pain and irritation of the vein Muscle cramps, weakness, tenderness or pain Problems with your liver or kidneys* Problems with certain blood cells or the way your blood clots* *These side effects may show up when you have a 	
show up when you have a blood test.	
Side effects	What to do
 Sudden swelling of the lips, face, throat or tongue, severe rash, swallowing or breathing problems. These are signs of severe allergic reaction (anaphylaxis) Diarrhoea that does not go away or stools that contain blood or mucus 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Side effects	What to do
Do not take any diarrhoea medicine without checking with the doctor.	
 Severe skin reaction, e.g., painful red areas, large blisters, peeling of your skin, and bleeding in the lips, eyes, mouth, nose or genital Sudden fever with chills, weakness in your limbs, sore throat, mouth or gum ulcers or bleeding gums Bleeding or bruising more than usual Confusion, memory loss or changes in personality Fever with cough, chest 	
pain, body aches with difficulty breathing	

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Zinforo contains

Active ingredient	Ceftaroline fosamil
Other ingredients	L-arginine

Do not take this medicine if you are allergic to any of these ingredients.

What Zinforo looks like

Zinforo is a pale yellowish-white to light yellow powder, which will be dissolved to a pale yellow solution before it is given to you.

Australian Registration Number: AUST R 192260.

Who distributes Zinforo

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

www.pfizer.com.au.

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