PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZINFORO® 600 mg Powder for concentrate for solution for infusion

Ceftaroline fosamil

Sugar free

Read all of this leaflet carefully before you are given ZINFORO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZINFORO has been prescribed for you personally and you should not share your ZINFORO with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZINFORO is and what it is used for

ZINFORO belongs to a group of medicines called antibiotics. ZINFORO works by killing bacteria.

ZINFORO is used to treat children (from birth) and adults with:

- infections of the skin and the tissues below the skin (known as acute bacterial skin and skin structure infections (ABSSSI)).
- an infection of the lungs called ‘pneumonia’ (known as community-acquired bacterial pneumonia).

2. What you need to know before you use ZINFORO

ZINFORO should not be administered to you:

- if you are hypersensitive (allergic) to ceftaroline fosamil or any of the other ingredients of ZINFORO (listed in section 6)
- if you are hypersensitive (allergic) to other antibiotics like penicillin, carbapenem or other cephalosporins. This is because you may also be allergic to ceftaroline

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

Warnings and precautions

Tell your doctor, nurse or health care provider before being given the injection:

- if you or your child have kidney problems
- if you or your child have ever had fits (seizures or convulsions)
- if you or your child have ever had severe diarrhoea after taking other antibiotics

You may develop signs and symptoms of severe skin reactions such as fever, joint pain, skin rash, red scaly rash, skin bumps that contain pus, blisters or peeling of skin, red circular patches often with central blisters on the trunk, ulcers of mouth, throat, nose, genitals and eyes. If this happens talk to your doctor or nurse immediately.

You may get another infection caused by another bacteria during or following treatment with ZINFORO.

Laboratory test

You may develop an abnormal laboratory test (called Coombs test) that looks for certain antibodies which may act against your red blood cells.

If any of the above applies to you (or you are not sure), talk to your doctor or nurse before receiving ZINFORO.

Other medicines and ZINFORO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

Tell your doctor before receiving ZINFORO if you are pregnant. Do not receive ZINFORO during pregnancy.

Tell your doctor before receiving ZINFORO if you are breastfeeding or are planning to breastfeed. Your doctor may ask you to stop breastfeeding during treatment with ZINFORO.

You should not breastfeed your baby whilst on treatment with ZINFORO.

Driving and using machines

ZINFORO may cause dizziness which may affect your ability to drive and use machines.

It is not always possible to predict to what extent ZINFORO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZINFORO affects them.

3. How to use ZINFORO

You will not be expected to give yourself ZINFORO. It will be given to you by a person who is qualified to do so.

How much to use

The usual 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.

Your doctor will tell you how long your or your child's treatment with ZINFORO will last. This will depend on the type of infection you have.

If you have the impression that the effect of ZINFORO is too strong or too weak, tell your doctor or pharmacist.

Patients with kidney problems

If you or your child has kidney problems, your doctor may lower your dose because ZINFORO is removed from the body by the kidneys.

Use in children

The usual recommended dose for children depends on the age and weight of the child. ZINFORO is given every 8 or 12 hours.

If you use more ZINFORO than you should

Since a health care provider will administer ZINFORO he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of ZINFORO

Since a health care provider will administer ZINFORO, it is unlikely that the dose will be missed.

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 ZINFORO, ask your doctor, pharmacist or nurse.

4. Possible side effects

ZINFORO can have side effects.

Not all side effects reported for ZINFORO are included in this leaflet. Should you or your child's general health worsen or if you experience any untoward effects while receiving ZINFORO, please consult your health care provider for advice.

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

- Sudden swelling of your 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 stool that contains blood or mucus. This can happen during or after treatment with ZINFORO stops. In this situation, you should not take medicines that stop or slow bowel movement.

Frequent side effects

- headache
- feeling dizzy
- pain and irritation in the veins
- diarrhoea, stomach pain
- feeling sick (nausea) or being sick (vomiting)
- more enzymes produced by your liver (as shown in blood tests)
- itching, skin rash
- redness, pain or swelling where the injection was given
- fever
- 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.

Less frequent side effects

- bleeding or bruising more than usual. This may be because the level of platelets in your blood has dropped (thrombocytopenia).
- a decrease in the number of a certain type of white blood cells in your blood (leukopenia)
- anaemia (decrease in the number of red blood cells in your blood)
- raised itchy rash (hives)
- an increase in the level of creatinine in your blood. Creatinine shows how well your kidneys are working.
- changes in tests which measure how well your blood clots

Other side effects

- 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.
- a decrease in the number of a certain type of white blood cells in your blood (neutropenia)
- an increase in the number of certain white blood cells in your blood (eosinophilia)
- changes in your mental state (encephalopathy) such as confusion, reduced level of consciousness, abnormal movements or fits – these have occurred in people when the dose they are given is too high, particularly in people with kidney problems
- a form of lung disease where eosinophils (a form of white blood cell) appear in the lung in increased numbers (eosinophilic pneumonia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or nurse.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZINFORO.

5. How to store ZINFORO

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in the original container.

Do not use vials after the expiry date on the container.

Your doctor or the hospital will normally store ZINFORO. The staff are responsible for the storing, dispensing and disposing of ZINFORO in the correct way.

6. Contents of the pack and other information

What ZINFORO contains

- The active substance is ceftaroline. Each vial contains ceftaroline fosamil 600 mg equivalent to ceftaroline 530 mg.
- The other ingredient is L-arginine.

What ZINFORO looks like and contents of the pack

A pale yellowish-white to light yellow powder, sterile and pyrogen free.

Powder in a glass vial closed with a rubber stopper and aluminium seal with flip-off cap.

Supplied in packs of 10 vials.

Holder of Certificate of Registration

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