

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA622 trade name] [†]
Ceftriaxone (sodium)

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HA622 trade name] is and what it is used for
2. What you need to know before you take [HA622 trade name]
3. How to take [HA622 trade name]
4. Possible side effects
5. How to store [HA622 trade name]
6. Contents of the pack and other information

1. What [HA622 trade name] is and what it is used for

[HA622 trade name] is an antibiotic used to treat some bacterial infections in people living with HIV/AIDS. It kills bacteria that cause infections.

The active ingredient in [HA622 trade name] is ceftriaxone, which belongs to a group of medicines called cephalosporins.

[HA622 trade name] is used to treat:

- infections of the
 - brain (meningitis)
 - lungs
 - abdomen (belly)
 - urinary tract and kidneys
 - bones and joints
 - skin or soft tissue
 - heart
- gonorrhoea, syphilis (sexually transmitted diseases)

It can be given to treat:

- bacteria in the blood
- patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection
- infections of the chest in adults with chronic bronchitis
- Lyme disease (caused by tick bites)
- prevent infections during surgery

[†]Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

2. What you need to know before you are given [HA622 trade name]

You must not be given [HA622 trade name] if you:

- are allergic (hypersensitive) to ceftriaxone.
- have had a sudden or severe allergic reaction to penicillin or similar antibiotics. The signs include sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly.

[HA622 trade name] must not be given to babies if:

- the baby is premature.
- the baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes), or is to be given an injection or a drip that contains calcium.

Talk to your health care provider as soon as possible, if this applies to you.

Warnings and precautions

Talk to your health care provider before you are given [HA622 trade name] if you:

- have recently received or are about to receive an injection or a drip that contains calcium
- have recently had diarrhoea after having an antibiotic medicine or if you have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- have liver or kidney problems
- have gall stones or kidney stones
- have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness).
- are on a low sodium diet.

Ask your health care provider if you are not sure if any of the above apply to you.

If you need a blood or urine test

If you are given [HA622 trade name] for a long time, you may need to have regular blood tests. [HA622 trade name] can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

- Tell the person taking the sample that you have been given [HA622 trade name].

Children

If [HA622 trade name] is to be given to a child, talk to your health care provider if the child has recently been given or is to be given an injection or a drip that contains calcium.

Other medicines and [HA622 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular, tell your health care provider if you are being treated with:

- an anticoagulant (to stop blood clots) such as warfarin
- a type of antibiotic called an aminoglycoside
- an antibiotic called chloramphenicol (used to treat infections, particularly of the eyes)

They may affect how well [HA622 trade name] works or [HA622 trade name] may affect their effect.

Pregnancy and breast-feeding

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before this medicine is given to you.

Driving and using machines

[HA622 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

If you are on a sodium-restricted diet

[HA622 trade name] contains sodium (main component of cooking salt). The amount of sodium you receive depends on the dose of [HA622 trade name]. Speak to your health care provider if you are on a sodium-restricted diet.

Other ingredients of [HA552 trade name]

Each gram of [HA622 trade name] contains 3.6 mmol sodium. This should be taken into consideration in patients on a controlled sodium diet. [HA622 trade name] contains 83 mg sodium per dosage unit, equivalent to 4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How [HA622 trade name] is given

[HA622 trade name] will be given to you by a health care provider, as a drip into a vein (an *intravenous infusion*) or as an injection directly into a vein or into a muscle.

Your health care provider will work out the right dose for you. You will be treated with [HA622 trade name] for as long as it takes to properly treat your infection.

The usual dose in **adults and adolescents older than 12 years and weighing at least 50 kg** is 1 to 2 g once a day depending on the type of infection. If you have a severe infection, your health care provider may give you a higher dose. When high doses are needed, your health care provider may decide to split the dose and give half the dose every 12 hours.

For **newborn babies, infants and children up to 12 years of age and weighing less than 50 kg**, the health care provider will work out the correct dose of [HA622 trade name], based on the patient's weight and the type of infection. [HA622 trade name] is usually given as a single dose once daily. When high doses are needed, your health care provider may split the dose and give half the dose every 12 hours.

People with liver and kidney problems

Your health care provider will decide how much [HA622 trade name] you need and adjust your treatment depending on the severity of the liver and kidney disease.

If you are given more or less [HA622 trade name] than you should

As this medicine is given by a health care provider, it is unlikely that you will be given too much or too little. If you have been given an extra dose, or missed one, **tell your health care provider straight away**.

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

4. Possible side effects

Like all medicines, [HA622 trade name] can cause side effects, although not everybody gets them.

If you notice any of the following, **stop taking [HA622 trade name] and tell your health care provider immediately** as you may need urgent treatment:

- severe allergic reactions
Signs may include:
 - sudden swelling of the face, throat, lips or mouth
 - breathing difficulty
 - sudden swelling of the hands, feet and ankles.
- severe skin rash
Signs may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly of mucous membranes (the lining of eyes, nose, mouth and genitals).

Other side effects of [HA622 trade name] are listed below according to how likely they are. Tell your health care provider if you get any of these side effects, especially if it gets serious, or if you notice any other unexpected or unusual effects not listed in this leaflet.

Common side effects (may affect up to 1 in 10 people):

- loose stools or diarrhoea
- rash
- blood tests showing changes in your liver function
- blood tests showing changes in the number of white blood cells (cells that help the body to fight infections) such as a decrease of leucocytes and an increase of eosinophils
- blood tests showing increase in the number of blood cells that affect blood clotting (platelets)

Uncommon side effects (may affect up to 1 in 100 people):

- fungal infections (for example, thrush affecting the vagina)
- anaemia (low red blood cell count which can make skin pale and cause weakness or breathlessness)
- problems with the way your blood clots. Signs may include bruising easily, and pain and swelling of your joints.
- headache
- dizziness
- feeling sick or being sick
- pruritis (itching)
- pain or a burning feeling along the vein where [HA622 trade name] has been given. Pain where the injection was given.
- high temperature (fever)
- blood tests showing decrease in the number of granulocytes (specialised white blood cells)
- blood tests showing changes in your kidney function (creatinine)

Rare side effects (may affect up to 1 in 1000 people):

- severe diarrhoea containing blood or mucus (antibiotic-associated colitis including pseudomembranous colitis) which, very rarely, may be life-threatening
- brain disorder caused by infection or harmful substances (encephalopathy)
- difficulty breathing caused by narrowing of the airways (bronchospasm)
- a lumpy, itchy rash (hives)
- blood or sugar in the urine
- swelling (of the hands, feet, ankles, lips, mouth or throat)
- shivering

Very rare side effects (may affect up to 1 in 10 000 people):

- fits (convulsions)

Side effects whose frequency is **not known**:

- infections caused by resistant bacteria
- a form of anaemia where red blood cells are destroyed (haemolytic anaemia)
- severe decrease in granulocytes (specialised white blood cells)
- allergic reactions, including reactions caused by the antibiotic killing certain types of bacteria (Jarish-Herxheimer reaction)
- sensation of dizziness (spinning or falling over)
- inflammation of the pancreas (pancreatitis). Signs include severe pain in the stomach which spreads to your back.
- inflammation of the mucous lining of the mouth (stomatitis)
- inflammation of the tongue (glossitis). Signs include swelling, redness and soreness of the tongue.
- problems with your gallbladder, which may cause pain, feeling sick and being sick.

- liver inflammation (hepatitis)
- brain condition that may occur in newborn babies with severe jaundice (kernicterus)
- serious skin reactions involving blistering and other effects throughout the body
- kidney problems which may cause pain when passing water (urine) or low output of urine
- false positive result in a Coombs' test (a test for some blood problems)
- false positive result for galactosaemia (an abnormal build-up of the sugar galactose)
- [HA622 trade name] may interfere with some types of blood glucose tests – check with your health care provider

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [HA622 trade name]

Unopened vials:

Do not store above 30°C. Keep the container in the outer carton in order to protect from light.

After reconstitution:

The constituted product as well as further diluted product should be used immediately after preparation. If not used immediately, the solutions in glass bottles or PVC bags should be used within 6 hours when stored at 30°C and 24 hours when stored at 2-8°C.

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

This medicine must not be used after the expiry date stated on the label after {EXP}. The expiry date refers to the last day of that month.

This medicine must not be used if description of the visible signs of deterioration.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [HA622 trade name] contains

- The active ingredient is ceftriaxone(sodium).

What [HA622 trade name] looks like and contents of the pack

[HA622 trade name] is provided as a sterile almost white or yellowish crystalline powder in a Type I glass vial (30 ml) closed with grey bromobutyl stoppers then capsulated with aluminium flip-off caps.

[HA622 trade name] is packed in 30ml vial (1 x10's vial per box).

Supplier and Manufacturer

Supplier

Sinopharm Zhijun (Shenzhen) Pharmaceutical
Co., Ltd
No. 16, Lanqing Yilu, Hi-Tech Zone
Guanlan, Longhua New District
Shenzhen, China
Tel: +86 400-880-2335
E-mail: vip@szzhijun.com

Manufacturer

Sinopharm Zhijun (Shenzhen) Pharmaceutical
Co., Ltd
No. 16, Lanqing Yilu, Hi-Tech Zone
Guanlan, Longhua New District
Shenzhen, China
Tel: +86 400-880-2335
E-mail: vip@szzhijun.com

For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>