

Ceftriaxone Alphapharm

contains the active ingredient ceftriaxone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ceftriaxone Alphapharm.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. Your doctor has been provided with full information and can answer any questions you may have.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Ceftriaxone Alphapharm against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Follow your doctor's advice even if it differs from what is in this leaflet.

Keep this leaflet with your medicine.

You may need to read it again.

What Ceftriaxone Alphapharm is used for

Ceftriaxone Alphapharm belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection or by stopping bacteria from growing.

Ceftriaxone Alphapharm is used to treat infections in different parts of the body caused by bacteria.

Ceftriaxone Alphapharm is also used to prevent infections before, during and after surgery.

Ceftriaxone Alphapharm will not work against infections caused by viruses such as colds or the flu.

Ask your doctor if you have any questions about why Ceftriaxone Alphapharm has been prescribed for you.

Your doctor may have prescribed Ceftriaxone Alphapharm for another reason.

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

Ceftriaxone Alphapharm is not addictive.

Before you are given Ceftriaxone Alphapharm

When you must not be given it

Do not use Ceftriaxone Alphapharm if:

- **you have had an allergic reaction to ceftriaxone, other cephalosporins or any of the ingredients listed at the end of this leaflet**

Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, dry skin, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles.

- **you have had a serious allergic reaction to penicillins.**

You may have an increased chance of being allergic to Ceftriaxone Alphapharm if you are allergic to penicillins.

In newborns, Ceftriaxone Alphapharm should not be given if they require (or are expected to require) treatment with calcium containing intravenous solutions, including parenteral nutrition (intravenous nutrition).

Ceftriaxone Alphapharm should not be given to preterm newborns or newborns with certain liver disorders.

If you are not sure if you should start using Ceftriaxone Alphapharm, contact your doctor.

Before you are given it

Your doctor must know about all of the following before you are given Ceftriaxone Alphapharm.

You must tell your doctor if:

1. **you have any type of allergic reaction to penicillin medicines**
You may have an increased chance of being allergic to Ceftriaxone Alphapharm if you are allergic to penicillins.
2. **you have had an allergy or over-reaction to lignocaine or other anaesthetic drugs**
These substances may be used to dissolve Ceftriaxone Alphapharm before administration.
3. **you are allergic to any other medicines or substances such as foods, preservatives or dyes**
4. **you have or have ever had any medical conditions including:**
 - kidney disease
 - bowel conditions, e.g. inflammation of the large bowel
 - diarrhoea associated with previous use of antibiotics
 - previous infection of your intestine with a bacteria called *Clostridium difficile*.
5. **you are pregnant, intend to become pregnant, are breast feeding or plan to breast feed**
Your doctor will discuss the risks and benefits of using Ceftriaxone Alphapharm during pregnancy or when breast feeding.

If you have not told your doctor about any of the above, tell them before you are given Ceftriaxone Alphapharm.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines, when taken with Ceftriaxone Alphapharm, may interfere with each other. These include:

- chloramphenicol (Chloromycetin®, Chlorsig®)
- fluconazole, a medicine used to treat fungal infections
- amsacrine, a medicine used to treat cancer

These medicines may be affected by Ceftriaxone Alphapharm, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines altogether. Your doctor will advise you.

Talk to you doctor about the need for an additional method of contraception while using Ceftriaxone Alphapharm.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Ceftriaxone Alphapharm.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given Ceftriaxone Alphapharm.

How Ceftriaxone Alphapharm is given

Ceftriaxone Alphapharm can be given in two ways:

- as a slow injection into a vein, or
- as a deep injection into a large muscle.

Ceftriaxone Alphapharm must only be given by a doctor or nurse.

Ceftriaxone Alphapharm should not be mixed or administered with calcium-containing solutions, even via different infusion lines.

Your doctor will decide what dose and how long you will receive Ceftriaxone Alphapharm for. This will depend on your infection and other factors, such as your weight. For most infections, Ceftriaxone Alphapharm is usually given once a day. The length of treatment is usually 4-14 days.

Sometimes a single dose of Ceftriaxone Alphapharm is required for the treatment and prevention of certain infections.

If too much Ceftriaxone Alphapharm is given, you may experience symptoms such as skin reactions, chills, diarrhoea, stomach upsets, headache or dizziness.

While you are using Ceftriaxone Alphapharm

Things you must do

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

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Ceftriaxone Alphapharm has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore or furry white mouth or tongue while using or soon after stopping Ceftriaxone Alphapharm, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Ceftriaxone Alphapharm allows fungi to grow and the above symptoms can occur. Ceftriaxone Alphapharm does not work against fungi.

If you become pregnant while you are using Ceftriaxone Alphapharm, tell your doctor immediately.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using Ceftriaxone Alphapharm.

If you have to test your urine for sugar while you are being given Ceftriaxone Alphapharm, make sure your doctor knows which type of test you use.

Ceftriaxone Alphapharm may affect the results of some of these tests.

If you have any blood tests, tell your doctor you are being given Ceftriaxone Alphapharm. Complete blood counts should be done at regular intervals as Ceftriaxone Alphapharm may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Ceftriaxone Alphapharm.

Things you must not do

Do not give Ceftriaxone Alphapharm to anyone else even if they seem to have the same condition as you.

Do not use Ceftriaxone Alphapharm to treat other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Ceftriaxone Alphapharm affects you.

Ceftriaxone Alphapharm generally does not cause any problems with your ability to drive or operate machinery. However, as with many other medicines, Ceftriaxone Alphapharm may cause dizziness in some people.

Storage

Ceftriaxone Alphapharm will be stored in the pharmacy or on the ward.

The powder for injection is kept in a cool, dry place protected from light and moisture, where the temperature stays below 25°C.

The reconstituted solution should be used immediately, but if necessary, can be kept in a refrigerator between 2°C and 8°C for not more than 24 hours after mixing. Do not freeze.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are receiving Ceftriaxone Alphapharm.

As with all prescription medicines, it is possible that Ceftriaxone Alphapharm will cause you to experience some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

While using Ceftriaxone Alphapharm

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

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina sometimes with a white discharge
- a hard lump, swelling, pain or tenderness at the injection site
- diarrhoea, feeling sick, vomiting
- headache or dizziness
- taste disturbances
- fast or irregular heart beat.

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- severe skin rash, itching or hives
- red, peeling or flaking of the skin
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles

- tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes
- severe diarrhoea (that may contain blood and mucous), stomach pain, and fever

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

After finishing Ceftriaxone Alphapharm

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Ceftriaxone Alphapharm:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. You may need urgent medical attention. However, these side effects are rare.

Do not take any diarrhoea medicine without first checking with your doctor.

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

Tell your doctor if you notice anything else that is making you feel unwell.

Overdosage of the medicine

As your dose of Ceftriaxone Alphapharm will be determined and administered by a medical specialist, the chance of receiving an overdose is most unlikely. However, if an overdose should be given, your specialist will give the appropriate treatment.

Product description

What it looks like

Ceftriaxone Alphapharm is a white to slightly yellow powder, which will be reconstituted before being injected.

Ceftriaxone Alphapharm is available in packs 5 vials (1000 mg and 2000 mg).

Ingredients

Each vial contains 1000 mg or 2000 mg of ceftriaxone, as the sodium salt.

Ceftriaxone Alphapharm does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

Ceftriaxone Alphapharm is supplied by:

Alphapharm Pty Limited
(ABN 93 002 359 739)
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.alphapharm.com.au

Medical Information
Phone: 1800 028 365

Australian registration numbers:

1000 mg vial -
AUST R 164920
2000 mg vial -
AUST R 164917

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