Package leaflet: Information for the user

Cefixime FrostPharma 20 mg/ ml granules for oral suspension

cefixime

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cefixime FrostPharma is and what it is used for

Cefixime FrostPharma contains an active substance called cefixime. This belongs to a group of antibiotics called “cephalosporins”, which are used for treating infections caused by bacteria.

Cefixime FrostPharma is used in children above 6 months, adolescents and adults to treat:
- sinus infection
- infection of the middle ear
- throat infection
- infection causing sudden worsening of long-standing bronchitis
- lung infections (pneumonia) acquired outside of hospital
- infections in the urinary tract including some kidney infections

2. What you need to know before you use Cefixime FrostPharma

Do not use Cefixime FrostPharma
- if you are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to any other cephalosporin antibiotics,
- if you have had a severe allergic reaction to penicillin antibiotic or to any other beta-lactam type of antibiotic (such as carbapenems or monobactams).

Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Cefixime FrostPharma.

Warnings and precautions
Talk to your doctor or pharmacist before using Cefixime FrostPharma if:
- you have ever had colitis (inflammation in the large intestine),
- you have kidney or nervous system problems (see section 4),
- your child is under the age of 6 months.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Cefixime FrostPharma is not suitable for everyone.

Before you take Cefixime FrostPharma you should tell your doctor:
- if you have ever had any allergic reaction to penicillin, carbapenem antibiotics or to any other beta-lactam type of antibiotics. An allergic reaction may include rash, itching, difficulty in swallowing or breathing or swelling of the face, lips, throat and tongue. Not all people who are allergic to penicillin are allergic to cephalosporins. However, you should take special care if you have ever had an allergic reaction to any beta-lactam antibiotic. This is because you might also be allergic to this medicine.
- if you develop a severe allergic reaction or anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness) after using Cefixime FrostPharma, the medicine must be discontinued and appropriate treatment should be given.
- if you are taking other medicines which are known to be harmful to your kidneys. Also inform your doctor if you have any kidney problems. Your doctor may perform certain test regularly to measure how well your kidneys are working during the treatment with Cefixime FrostPharma.
- if you are taking anticoagulants (blood thinning medicines) such as warfarin Cefixime may cause problems with blood clotting and may increase the time taken for the blood to clot.
- if you have severe or persistent diarrhoea with stomach pain or cramps during or shortly after treatment with Cefixime FrostPharma. If this occurs, stop taking this medicine and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken.

If you develop syndrome known as DRESS syndrome or Stevens-Johnson syndrome or skin reaction known as toxic epidermal necrolysis (see section 4. Possible side effects) while you are taking Cefixime FrostPharma, stop taking this medicine and contact your doctor immediately.

Having a course of Cefixime FrostPharma can temporarily increase the risk that you can get infections caused by other sort of germs on which Cefixime FrostPharma does not act on. For example, thrush (infection caused by a yeast germ called *Candida*) may occur.

Effect on laboratory tests
If you are to take any blood or urine tests, inform your doctor that you are using Cefixime FrostPharma, as cefixime can alter the results of:
- some urine tests for sugar (such as Benedict's or Fehling's tests). If you have diabetes and routinely test for urine, tell your doctor. This is because other tests may have to be used to monitor your diabetes while you are having this medicine.
- some urine tests for ketones. Tell your doctor that you are using Cefixime FrostPharma because other tests may have to be used.
- a blood test for antibodies called the direct Coomb´s test.

Other medicines and Cefixime FrostPharma
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist if you are taking:
- medicines which are known to be harmful to your kidneys like:
    - antibiotics including aminoglycoside antibiotics, colistin, polymyxin and viomycin,
    - medicines that increase the amount of urine your body produces (diuretics) such as ethacrynic acid or furosemide.
- Nifedipine, a medicine used for the treatment of high blood pressure or heart problems,

Cefixime FrostPharma with food and drink
Cefixime FrostPharma may be taken with or without food.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Cefixime FrostPharma has no known influence on the ability to drive and use machines.

Cefixime FrostPharma contains sucrose and sodium benzoate (E 211)
This medicine contains 0.5 g of sucrose per ml reconstituted suspension. This should be taken into account by patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 0.5 mg sodium benzoate (E 211) per ml reconstituted suspension. Sodium benzoate (E 211) may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains less than 1 mmol sodium (23 mg) per ml reconstituted suspension, that is to say essentially 'sodium-free'.

3. How to use Cefixime FrostPharma

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose your doctor prescribes depends on the type of infection and how bad the infection is. It also depends on how well your kidneys are working. Your doctor or pharmacist will explain this to you.

The reconstituted suspension can be given with or without food. Do not dilute the suspension with any other drink.

The usual dose is:

Adults
400 mg once daily (= 20 ml of reconstituted suspension) as a single dose or 200 mg twice daily (= 10 ml of reconstituted suspension) every 12 hours.

Elderly
No change in dose is needed for elderly patients, provided the kidneys are normal.

Use in children and adolescents

Adolescents 12 years of age and older
Adolescents 12 years of age and older may be given the same dose as adults.

Children under 12 years
Cefixime FrostPharma should be given as 8 mg/kg body weight/day (maximum 400 mg/day), either as a single dose or in two equal divided doses every 12 hours. The dosing recommendations for reconstituted solution are given in the following table:

Body weight	**Daily dose (ml) Once daily**	**Daily dose (ml) Twice daily**	**Daily dose (mg)**
6.0 kg-9 kg (for infants above 6 months)	1 x 2.5 ml	2 x 1.25 ml	50 mg
10.0 kg	4 ml	2 x 2 ml	80 mg
12.5 kg	5 ml	2 x 2.5 ml	100 mg
15.0 kg	6 ml	2 x 3 ml	120 mg
17.5 kg	7 ml	2 x 3.5 ml	140 mg
20.0 kg	8 ml	2 x 4 ml	160 mg
22.5 kg	9 ml	2 x 4.5 ml	180 mg
25.0 kg	10 ml	2 x 5 ml	200 mg

27.5 kg	11 ml	2 x 5.5 ml	220 mg
30.0 kg	12 ml	2 x 6 ml	240 mg
32.5 kg	13 ml	2 x 6.5 ml	260 mg
35.0 kg	14 ml	2 x 7 ml	280 mg
37.5 kg	15 ml	2 x 7.5 ml	300 mg
40.0 kg	16 ml	2 x 8 ml	320 mg
42.5 kg	17 ml	2 x 8,5 ml	340 mg
45.0 kg	18 ml	2 x 9 ml	360 mg
47,5 kg	19 ml	2 x 9.5 ml	380 mg
50.0 kg	20 ml	2 x 10 ml	400 mg

People with kidney problems
If you have severe kidney problems, your doctor may lower your dose. It is recommended to not exceed a dose of 200 mg once daily.

In children under 12 years with severe kidney problems, , a dose of 4 mg cefixime/kg body weight should be given only once daily.

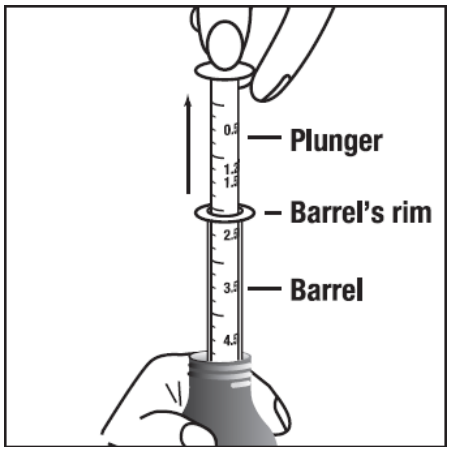
Preparation of the suspension
Information for healthcare professionals
To reconstitute, use the plastic measuring cup provided in the cardboard box. Add 40 ml of purified water divided into two portions shaking after each addition.

The reconstituted suspension is an almost white to pale yellow viscous liquid.

Information for the user
Shake the medicine bottle well before each use.

A graduated plastic pipette is used for measuring the required prescribed amount of medicine. The plastic pipette is included in the package.

How to use the pipette:
1. After the suspension has been reconstituted by the healthcare professional, shake the bottle well before use and remove the bottle cap.
2. Remove the cap from the pipette and insert the pipette into the bottle.
3. Pull the plunger up the barrel until the barrel’s rim is aligned with the mark on the plunger corresponding to the required dose.



4. Remove the pipette from the bottle.
5. With the patient seated in an upright position, place the tip of the pipette just inside the patient's mouth, pointing towards the inside of the cheek.

6. Press the plunger of the pipette in slowly to expel the medicine without causing choking. Do NOT squirt the medicine out in a jet.
7. Repeat steps 2-6 in the same way until the whole dose has been given.
8. After giving the dose put back the cap on the bottle. Dismantle the pipette and wash it thoroughly in fresh drinking water. Allow the plunger and the barrel to dry naturally.

Duration of treatment
The usual course of treatment is 7-10 days. This may be continued for up to 14 days according to the severity of the infection.
For acute uncomplicated cystitis in women, the treatment period is 1-3 days.

If you use more Cefixime FrostPharma than you should
If you or your child have taken more of this medicine than you should, talk to your doctor or contact your nearest hospital emergency department immediately.

If you take higher dose of Cefixime FrostPharma than you should, there is a risk of decreased consciousness, abnormal movements and convulsions.

If you forget to use Cefixime FrostPharma
If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and go back to your regular dosing schedule.
Do not take a double dose.

If you stop using Cefixime FrostPharma
It is important that you take this medicine until you finish the prescribed course. You should not stop taking Cefixime FrostPharma just because you feel better. If you stop too soon, the infection may start again. If the person being treated still feels unwell at the end of the prescribed course of treatment or feels worse during treatment, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects are important and will require immediate action if you experience them. You should stop taking Cefixime FrostPharma and see your doctor immediately if the following symptoms occur:

Very rare (may affect up to 1 in 10,000 people):'
- watery and severe diarrhoea that may also be bloody
- sudden severe allergic reactions (anaphylactic shock) such as skin rash or hives, itchiness, swelling of the face, lips, tongue or other parts of the body, tightness of the chest, wheezing and collapse
- severe skin illness with blistering of the skin, mouth, eyes and genitals (Stevens Johnson syndrome, toxic epidermal necrolysis).

Not known (frequency cannot be estimated from the available date)
- Severe skin eruption, fever, enlarged lymph nodes, increase in the numbers of white blood cells called eosinophils (DRESS syndrome)

The following side-effects have also been reported:

Common (may affect up to 1 in 10 people):
- diarrhoea

Uncommon (may affect up to 1 in 100 people):
- headache
- nausea
- vomiting
- abdominal (tummy) pain
- changes in blood tests that check how your liver is working
- skin rash

Rare (may affect up to 1 in 1,000 people):
- an increased chance that you can get infections caused by germs that cefixime does not act on. For example, thrush
- increase in the numbers of white blood cells called eosinophils
- allergic reaction
- loss of appetite
- dizziness
- flatulence (wind)
- itchy skin
- inflammation of mucus (moist) linings such as the mouth and / or other internal surfaces
- fever
- changes in blood tests that check how your kidneys are working

Very rare (may affect up to 1 in 10,000 people):
- fall in the number of different cells in the blood (symptoms can include tiredness, new infections and easy bruising or bleeding)
- allergic reaction characterised by skin rashes, fever, joint pains and enlarged organs
- restlessness and increased activity
- liver problems including jaundice (yellowing of the skin or whites of the eyes)
- inflammation of the kidney

Not known (frequency cannot be estimated from the available data)
- rise in the number of blood platelets (thrombocytosis)
- decrease in the number of a type of white blood cells (neutropenia)
- dyspepsia
- skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.
- Treatment with cefixime, particularly in elderly patients or in patients with serious kidney or nervous system problems, has been known to cause decreased consciousness, movement disorders and convulsions (encephalopathy).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefixime FrostPharma

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

Unreconstituted product should be stored below 25ºC.
Reconstituted suspension: Store below 25°C for 14 days. Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Cefixime FrostPharma contains

- The active substance is cefixime trihydrate. Each ml of reconstituted oral suspension contains 20 mg of cefixime (as cefixime trihydrate).
- The other ingredients are: sucrose, xanthan gum, sodium benzoate (E 211), flavour durarome orange (flavouring ingredients, maize maltodextrin, sucrose, modified corn starch, acacia gum (arabic gum), citric acid esters of mono- and diglycerised of fatty acids, silicon dioxide (E 551)).

What Cefixime FrostPharma looks like and contents of the pack

Cefixime FrostPharma granules for oral suspension are almost white to pale yellow granules.

The granules for oral suspension are packed in a brown neutral glass bottle, with an aluminium screw cap with a polyethylene sealing.

The bottle is placed in a cardboard box, including a polypropylene measuring cup graduated on 40 ml for reconstitution and a plastic 5 ml pipette for dosing (polystyrene plunger and low-density polyethylene (LDPE) body and protection cap) with a scale from 0.5 ml to 5 ml and graduations on each 0.25ml, imprinted on the plunger.

Pack sizes: 60 ml of oral suspension (reconstituted)

Not all pack sizes may be marketed.

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This leaflet was last revised 2026-06-26

<Detailed information on this medicine is available on the website of {name of Member State Agency (link)}>