
CLEAN PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CEFUROXIME 750 mg FKSA (Powder for Solution for Injection)

CEFUROXIME 1500 mg FKSA (Powder for Solution for Injection/Infusion)

Sugar free

Read all of this leaflet carefully before you are given CEFUROXIME FKSA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What CEFUROXIME FKSA is and what it is used for
2. What you need to know before you receive CEFUROXIME FKSA
3. How CEFUROXIME FKSA will be given
4. Possible side effects
5. How to store CEFUROXIME FKSA
6. Contents of the pack and other information

1. What CEFUROXIME FKSA is and what it is used for

CEFUROXIME FKSA belongs to the antibiotic group of medicines known as the cephalosporins.

CEFUROXIME FKSA is used for a variety of bacterial infections. These include respiratory, ear, nose and throat infections, urinary infections, disorders affecting the female reproductive organs, gonorrhoea (sexually transmitted diseases) and soft tissue infection. CEFUROXIME FKSA may also be used to prevent certain infections before surgery where infection may occur.

2. What you need to know before you receive CEFUROXIME FKSA

Do not receive CEFUROXIME FKSA:

- If you are allergic to cefuroxime or other cephalosporin antibiotics, penicillin and other β-lactam antibiotics; or any of the components of CEFUROXIME FKSA (listed in section 6).
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after treatment with cefuroxime or any other cephalosporin antibiotics.

Warnings and Precautions

Take special care with CEFUROXIME FKSA:

- **CEFUROXIME FKSA should be administered with caution in patients who are generally allergic. Please tell your doctor about all allergic reactions you have had previously, especially to medicines.**
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with cefuroxime treatment. Seek medical attention

immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

- Tell your doctor if you develop diarrhoea while using CEFUROXIME FKSA. This may be an indication of inflammation of the large intestine (colitis). Please consult your doctor immediately if you have diarrhoea for longer than two weeks, bloody or watery diarrhoea, abdominal cramps and pain. Do not take medicines to stop or slow the diarrhoea.
- Tell your doctor if you have a kidney or liver disorder.
- Tell your doctor if you have a disorder called porphyria.

CEFUROXIME FKSA may interfere with certain blood and urine tests. Please tell your doctor you are using CEFUROXIME FKSA before having any laboratory tests done.

CEFUROXIME FKSA should not be given to babies under 3 months of age.

Other medicines and CEFUROXIME FKSA

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

Certain medicines may interact with CEFUROXIME FKSA. In these cases it may be necessary to change the dose or interrupt the treatment of one of the medicines.

Medicines that affect the kidneys such as certain water tablets (e.g. furosemide) and aminoglycoside antibiotics (e.g. gentamicin) may interact with CEFUROXIME FKSA which may lead to kidney problems.

Probenecid (used for the treatment of gout) may increase the amount of CEFUROXIME FKSA in the blood and increase the chance of side effects.

Not all the medicines that may interact with CEFUROXIME FKSA are listed above.

Contraceptive pills

Cefuroxime may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with CEFUROXIME FKSA you also need to use a barrier method of contraception (such as a condom). Ask your doctor for advice.

Pregnancy, breastfeeding and fertility

Do not receive CEFUROXIME FKSA if you are pregnant, planning to become pregnant or breastfeeding. CEFUROXIME FKSA is excreted into breast milk and may affect your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice.

Driving and using machines

CEFUROXIME FKSA is not expected to affect your ability to drive a car or operate machinery.

It is not always possible to predict to what extent CEFUROXIME FKSA may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which CEFUROXIME FKSA affects you.

CEFUROXIME FKSA contains sodium

CEFUROXIME 750 mg FKSA contains 41,4 mg sodium per vial, equivalent to 2,1 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

CEFUROXIME 1500 mg FKSA contains 82,8 mg sodium per vial, equivalent to 4,15 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Tell your doctor if you are on a restricted salt diet.

3. How CEFUROXIME FKSA will be given

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

CEFUROXIME FKSA is given as an injection either into a vein (intravenous) or into a muscle (intramuscular). The dose range lies between 1,5 – 6,0 g/day.

Your doctor will decide on the correct dose to obtain the results needed. The dose of CEFUROXIME FKSA will be different for each patient, taking into account your condition and body weight.

Your doctor will tell you how long the treatment will be.

CEFUROXIME FKSA should not be given to babies less than 3 months old.

If you received more CEFUROXIME FKSA than you should

Since a healthcare provider will administer CEFUROXIME FKSA, he/she will control the dosage and it is unlikely that you will receive an incorrect dose. However, in the event of overdosage, your doctor will take appropriate supportive measures to treat the effects of overdosage.

4. Possible side effects

CEFUROXIME FKSA may have side effects.

Not all side effects reported for CEFUROXIME FKSA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CEFUROXIME FKSA, please consult your healthcare provider for advice.

If you experience the following, stop receiving CEFUROXIME FKSA and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- Irregular heart beat.
- Allergic reactions (swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, severe skin rashes).

A small number of people treated by CEFUROXIME FKSA get an allergic reaction or potentially serious skin reaction. Symptoms of these reactions include:

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

The above side effects are very serious. If you have them, you may have had a serious reaction to CEFUROXIME FKSA. You may need urgent medical attention or hospitalisation. These very serious side effects do not occur frequently.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Blistering, peeling or loosening of skin and mucous membranes. Your doctor will diagnose if this is a very serious, possibly life-threatening, condition known as Stevens Johnson syndrome.
- Stomach pains, diarrhoea for longer than two weeks or bloody or watery diarrhoea, abdominal cramps. Your doctor will diagnose whether you have pseudomembranous colitis, a very serious disorder (see above under **Take special care with CEFUROXIME FKSA*).***

- Black, tarry stools, chest pain, chills, cough, painful or difficult urination, unusual tiredness or weakness. These symptoms may be due to blood disorders, possibly eosinophilia, which may occur frequently.
- Sudden fever, rigors and sore throat. This may be due to a low white blood cell count (agranulocytosis). It is not known how often it occurs.
- Unusual bleeding or bruising (thrombocytopenia).
- Fever with rash, skin itching, redness, swelling or hives (allergic reaction).
- Fits (seizures).
- Hearing loss; mild to moderate.
- Trouble urinating or blood in urine, which may be due to a kidney problem known as interstitial nephritis.

These are all serious side effects. You may need urgent medical attention. Serious side effects do not occur frequently, unless specifically mentioned to occur frequently or that the frequency is unknown.

Tell your doctor if you notice any of the following:

Frequent side effects

- injection site pain, inflammation and tenderness.
- changes seen in blood test results:
  - increases in substances (enzymes) produced by the liver
  - changes in your white blood cell count (neutropenia or eosinophilia)
  - low levels of red blood cells (anaemia)
- Headache

Less frequent side effects

- Redness and swelling along a vein (cutaneous vasculitis)
- Side effects that may show up in blood tests:
  - low levels of white blood cells (leucopenia)
  - increase in bilirubin (a substance produced by the liver)
  - false positive Coomb's test (a test to check your blood for antibodies that attack red blood cells)

Side effects whose frequency is unknown

- Side effects that may show up in blood tests:
  - increase in levels of urea nitrogen and serum creatinine in the blood.

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

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CEFUROXIME FRESENIUS.

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CEFUROXIME FRESENIUS

Store all medicines out of reach of children.

Sterile powder for injection:

Store at or below 25 °C.

Keep the vials in outer carton to protect from light.

Reconstituted product:

Stable for 24 hours when stored at 2 – 8 °C.

Do not use after the expiry date stated on the label and carton.

(CEFUROXIME FKSA is for use in hospital only, your doctor, nurse or pharmacist will check this date.)

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets). (Your doctor or nurse will dispose of any medicine that is no longer required.)

6. Contents of the pack and other information

What CEFUROXIME FKSA contains

The active substance is cefuroxime:

CEFUROXIME 750 mg FKSA: Each vial contains 750 mg cefuroxime as cefuroxime sodium.

CEFUROXIME 1500 mg FKSA: Each vial contains 1500 mg cefuroxime as cefuroxime sodium.

Inactive ingredient: No other ingredients are present.

What CEFUROXIME FKSA looks like and contents of the pack

CEFUROXIME FKSA is a white or almost white powder in a glass vial/infusion bottle.

CEFUROXIME 750 mg FKSA: 15 mL type II, clear, colourless glass vial closed with grey rubber stoppers and blue aluminium/plastic caps, in packs of 10.

CEFUROXIME 1 500 mg FKSA: 20 mL type II, clear, colourless glass vials closed with red rubber stoppers and red aluminium/plastic caps, in packs of 10.

50 mL type II, clear, colourless glass infusion bottles closed with dark grey rubber stoppers and red aluminium/plastic caps, in packs of 10.

Holder of Certificate of Registration

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CEFUROXIME 750 mg FKSA: 42/20.1.1/0986

CEFUROXIME 1500 mg FKSA: 42/20.1.1/0737

Access to the corresponding Professional Information

The professional information will be printed and packed with the product.