PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CEFTRIAXONE 500 mg FKSA powder for solution for injection

CEFTRIAXONE 1 g FKSA powder for solution for injection

CEFTRIAXONE 2 g FKSA powder for solution for infusion

Ceftriaxone

Sugar free

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

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

What is in this leaflet:

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

CEFTRIAXONE FKSA is an antibiotic of the group of medicines called cephalosporins.

CEFTRIAXONE FKSA is given to adults and children (including new-born babies)**.** It works by killing susceptible bacteria that cause certain infections.

2. What you need to know before you use CEFTRIAXONE FKSA

Do not use CEFTRIAXONE FKSA

- If you are hypersensitive (allergic) to ceftriaxone or any of the other ingredients of CEFTRIAXONE FKSA (listed in section 6).
- If you have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). 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, chest pain and a severe rash that develops quickly.
- If you are allergic to lidocaine (lignocaine) and you are to be given CEFTRIAXONE FKSA as an injection into a muscle, as it is mixed with lidocaine (lignocaine) solution for intramuscular injection.

  Do not receive CEFTRIAXONE FKSA solution for injection intravenously if it contains lidocaine.
- Your baby must not be given CEFTRIAXONE FKSA if:
  - your baby is premature;
  - your baby is new-born (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or he/she is to be given a product that contains calcium into their veins.

Warnings and precautions

Tell your doctor or healthcare provided before being given CEFTRIAXONE FKSA:

- if you experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4 “Possible side effects”).
- if you have recently received or are about to be administered products that contain calcium;
- if you 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);
- if you have recently had diarrhoea after having an antibiotic medicine or if you have ever had problems with your gut (inflammation of the bowel);
- if you have liver or kidney problems;
- if you have gall stones or kidney stones;
- if you are on a low sodium diet.

<u>If you need a blood or urine test:</u>

If you are given CEFTRIAXONE FKSA for a long time, you may need to have regular blood tests. CEFTRIAXONE FKSA can affect the results of urine tests for sugar and a blood test known as the Coombs test. The Coombs test looks for antibodies that may stick to your red blood cells and cause red blood cells to die too early.

Tell the healthcare provider taking the sample that you have been given CEFTRIAXONE FKSA.

Elderly (65 years and older)

Encephalopathy (brain disease) has been reported with the use of ceftriaxone, as in CEFTRIAXONE FKSA (see Possible side effects), particularly in elderly patients with very weak kidney function or central nervous system disorders. If you notice an altered mental state, muscle jerks and fits, talk to your doctor as he/she may consider stopping your treatment with CEFTRIAXONE FKSA.

Children

Talk to your doctor or pharmacist or nurse before your child is administered CEFTRIAXONE FKSA if he/she has recently been given or is to be given a medicine that contains calcium into their vein.

Other medicines and CEFTRIAXONE FKSA

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

Effect of CEFTRIAXONE FKSA on other medicines:

Your doctor will know that ceftriaxone, as in CEFTRIAXONE FKSA, may not be given simultaneously with calcium containing intravenous solutions such as Ringer's lactate. Ceftriaxone and calcium may bind together in your blood and form a precipitate in your blood, which may damage your kidneys, lungs, or gallbladder.

Tell your doctor or pharmacist if you are taking:

- an antibiotic called chloramphenicol (used to treat infections, usually of the eye). Chloramphenicol may affect how well CEFTRIAXONE FKSA works.

Effect of CEFTRIAXONE FKSA on other medicines:

- warfarin (a blood thinner). CEFTRIAXONE FKSA may enhance the thinning effect and increase the risk of bleeding.

Effect of CEFTRIAXONE FKSA on laboratory tests:

Tell your healthcare provider if you have diabetes. CEFTRIAXONE FKSA can alter the results of (non-enzymatic) urine tests for sugar. Other tests may have to be used to monitor your diabetes while you are being treated with CEFTRIAXONE FKSA.

If you are having blood tests done, note that CEFTRIAXONE FKSA can alter the results of some blood tests (such as the Coombs' test).

Make sure that you tell the healthcare provider that you are being treated with CEFTRIAXONE FKSA when you go for any blood test.

Pregnancy and breastfeeding

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 before receiving CEFTRIAXONE FRESENIUS.

Pregnancy:

Safety in human pregnancy has not been established. Ceftriaxone crosses the placental barrier. You should not be given CEFTRIAXONE FKSA when you are pregnant.

Breastfeeding:

Ceftriaxone is excreted in the breastmilk. You should not breastfeed your baby if you have to use CEFTRIAXONE FKSA. If you do not want to stop breastfeeding, talk to your doctor about other alternatives.

Driving and using machines

You may get dizzy when you receive CEFTRIAXONE FKSA. You should not drive or operate machines until you know how CEFTRIAXONE FKSA affects you.

CEFTRIAXONE FKSA contains sodium

CEFTRIAXONE FKSA contains sodium.

Tell your doctor if you are on a controlled sodium diet.

3. HOW TO USE CEFTRIAXONE FKSA

Do not share medicine prescribed for you with any other person.

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

CEFTRIAXONE FKSA can be given as:

- a drip (intravenous infusion) or as an injection directly into a vein;
- into a muscle.

CEFTRIAXONE FKSA solution is prepared by your healthcare provider and will not be mixed with or given to you at the same time as calcium containing injections.

The usual dose is:

Your doctor will decide on a correct dose of CEFTRIAXONE for you. The dose will depend on the type of infection and how severe the infection is, what you weigh and how well your kidneys and liver are working. The number of days or weeks that you are given CEFTRIAXONE FKSA depends on what sort of infection you have.

Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):

- 1 to 2 g once a day depending on the severity and type of infection.

New-born babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:

- 20 – 80 mg CEFTRIAXONE FKSA for each kg of the child's body weight once a day depending on the severity and type of infection.
- Children with a body weight of 50 kg or more should be given the usual adult dose.

New-born babies (0-14 days):

- 20 – 50 mg CEFTRIAXONE FKSA for each kg of the child's body weight once a day depending on the severity and type of infection.

People with liver and kidney problems:

- You may be given a different dose to the usual dose. Your doctor will decide how much CEFTRIAXONE FKSA you will need and will check you closely depending on the severity of the liver and kidney disease.

If you use more CEFTRIAXONE FKSA than you should

Since a healthcare provider will administer CEFTRIAXONE FKSA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

In the unlikely event of an overdose, you may develop nausea, vomiting and diarrhoea.

If you forget to use CEFTRIAXONE FKSA

Since a healthcare provider will administer CEFTRIAXONE FKSA, it is unlikely that the dose will be missed.

If you stop using CEFTRIAXONE FKSA

It is important that you receive the whole course of treatment as prescribed. It should not be interrupted just because you feel well again. If the treatment is stopped too early the infection may start up again.

4. POSSIBLE SIDE EFFECTS

CEFTRIAXONE FKSA can have side effects.

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

If any of the following happens, tell your doctor immediately:

- **Severe allergic reactions**: some signs may be a sudden swelling of the face, throat, lips or mouth (this can make it difficult to breathe or swallow), sudden swelling of the hands, feet and ankles.
- **Chest pain** in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).
- **Severe allergic skin reactions**: some signs are a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement

(Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to CEFTRIAXONE FKSA. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting CEFTRIAXONE FKSA treatment for infections with spirochete such as Lyme disease.
- A brain disorder (encephalopathy), particularly in elderly patients. Some signs may be an altered mental state, muscle jerks and fits.
- Watery diarrhoea that lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation (colitis, pseudomembranous colitis) that can happen after taking antibiotics.
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back, nausea and vomiting.

These are all serious side effects. You may need urgent medical attention.

Other side effects

Frequent side effects

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
- Loose stools or diarrhoea.
- Changes in the results of blood tests for liver functions.
- Rash.

Less frequent

- Fungal infections (for example, thrush).
- A decrease in the number of white blood cells (granulocytopenia).
- Reduction in number of red blood cells (anaemia).
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
- Headache.
- Dizziness.
- Difficulty in breathing (bronchospasm).
- Feeling sick or being sick.
- Pruritis (itching).
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- Blood or sugar in your urine.
- Pain or a burning feeling along the vein where CEFTRIAXONE FKSA has been given. Pain where the injection was given.
- A high temperature (fever).
- Shivering.
- Oedema (fluid build-up).
- Abnormal kidney function test (blood creatinine increased).

Unknown frequency (frequency cannot be estimated from the available data)

- A secondary infection that may not respond to the antibiotic previously prescribed.
- Form of anaemia where red blood cells are destroyed (haemolytic anaemia).

- Haematoma (a bad bruise(s)) or bleeding.
- Petechiae (small red or purple spots caused by bleeding into the skin).
- Sweating
- Flushing
- Severe decrease in white blood cells (agranulocytosis).
- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the mucous lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder and/or liver, which may cause pain, nausea (feeling sick), vomiting (being sick), yellowing of the skin, itching, unusually dark urine and clay-coloured stools.
- A neurological condition that may occur in neonates with severe jaundice (kernicterus).
- Kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.
- A false positive result in a Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (an abnormal build-up of the sugar galactose).
- CEFTRIAXONE FKSA may interfere with some types of blood glucose tests - please check with your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse 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 CEFTRIAXONE FKSA.

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 CEFTRIAXONE FKSA

Store all medicines out of reach of children.

Store at or below 30 °C, keep vial or bottle in the outer carton in order to protect from light.

For single use only.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not be longer than the times stated above for the chemical and physical in-use stability. Chemical and physical in-use stability of the reconstituted product has been demonstrated for 12 hours at 25 °C and for 2 days at 2-8 °C.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets). This will help to protect the environment.

6. Contents of the pack and other information

What CEFTRIAXONE FKSA contains

- The active substance is ceftriaxone disodium hydrate.

Each CEFTRIAXONE 500 mg FKSA vial contains 0,5 g ceftriaxone (as disodium hydrate).

Each CEFTRIAXONE 1 g FKSA vial contains 1 g ceftriaxone (as disodium hydrate).

Each CEFTRIAXONE 2 g FKSA vial contains 2 g ceftriaxone (as disodium hydrate).

- There are no other ingredients present.

What CEFTRIAXONE FKSA looks like and contents of the pack

CEFTRIAXONE 500 mg FKSA: powder for solution for injection

CEFTRIAXONE 1 g FKSA: powder for solution for injection/infusion

CEFTRIAXONE 2 g FKSA: powder for solution for injection/infusion

An almost white or yellowish, crystalline powder.

The prepared solutions are light yellow to brownish yellow.

Do not use CEFTRIAXONE FKSA if you notice that the solution is not clear.

<u>CEFTRIAXONE 500 mg FKSA powder for solution for injection or infusion</u>

15 mL vial, glass, colourless Type II glass vials closed with rubber stoppers and flip-off caps.

Pack size of 1’s; 10’s or 25’s single dose vials.

Not all pack sizes may be marketed.

CEFTRIAXONE 1 g FKSA powder for solution for injection or infusion

15 mL vial, glass, colourless Type II glass vials closed with rubber stoppers and flip-off caps.

Pack size of 1's; 10's or 25's single dose vials.

Not all pack sizes may be marketed.

CEFTRIAXONE 2 g FKSA powder for solution for injection or infusion

15 mL vial, glass, colourless Type II glass vials closed with rubber stoppers and flip-off caps.

50 mL colourless Type II glass infusion bottles, closed with rubber stoppers and flip-off caps.

Pack size of 1's or 10's single dose vials or 1x single dose bottle.

Not all pack sizes may be marketed.

Holder of Certificates of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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Ceftriaxone 1 g FKSA: 48/20.1.1/0228

Ceftriaxone 2 g FKSA: 48/20.1.1/0229

Access to the corresponding Professional Information

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