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

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

3. How to use CEFTRIAXONE FKSA

4. Possible side effects

5. How to store CEFTRIAXONE FKSA

6. Contents of the pack and other information

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 breathe 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 provider 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 section 4 “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, 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 FKSA 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.
- Pruritus (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.

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. 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.

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

CEFTRIAXONE 2 g FKSA: powder for solution for 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</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

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 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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Registration numbers

CEFTRIAXONE 500 mg FKSA: 48/20.1.1/0227

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.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

CEFTRIAXONE 500 mg FKSA poeier vir oplossing vir inspuiting

CEFTRIAXONE 1 g FKSA poeier vir oplossing vir inspuiting

CEFTRIAXONE 2 g FKSA poeier vir oplossing vir infusie

Keftriaksoon

Suikervry

Lees die hele inligtingsblad aandagtig deur voordat CEFTRIAXONE FKSA aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy enige verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- CEFTRIAXONE FKSA is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad:

1. Wat is CEFTRIAXONE FKSA en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy CEFTRIAXONE FKSA gebruik
3. Hoe om CEFTRIAXONE FKSA te gebruik
4. Moontlike newe-effekte
5. Hoe om CEFTRIAXONE FKSA te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is CEFTRIAXONE FKSA en waarvoor word dit gebruik

CEFTRIAXONE FKSA is 'n antibiotikum van die groep medisyne genaamd kefalosporiene.

CEFTRIAXONE FKSA word aan volwassenes en kinders (insluitend pasgebore babas) gegee**.** Dit werk deur vatbare bakterieë wat sekere infeksies veroorsaak, dood te maak.

2. Wat jy moet weet voordat jy CEFTRIAXONE FKSA gebruik

Moenie CEFTRIAXONE FKSA gebruik nie

- Indien jy hipersensitief (allergies) is vir keftriaksoon of enige van die ander bestanddele van CEFTRIAXONE FKSA (gelys in afdeling 6).
- Indien jy 'n skielike of ernstige allergiese reaksie op penisillien of soortgelyke antibiotika (soos kefalosporiene, karbapeneme of monobaktame) gehad het. Tekens sluit in skielike swelling van die keel of gesig wat probleme met asemhaling of sluk kan veroorsaak, skielike swelling van die hande, voete en enkels, borspyn en 'n erge, vinnig ontwikkelende uitslag.
- Indien jy allergies is vir lidokaïen (lignokaïen) en jy moet CEFTRIAXONE FKSA as 'n inspuiting in 'n spier kry, want vir binnespierse inspuiting word dit met lidokaïen (lignokaïen) oplossing gemeng.

  Moet nie CEFTRIAXONE FKSA oplossing vir inspuiting binneaars ontvang as dit lidokaïen bevat nie.
- Jou baba moet nie CEFTRIAXONE FKSA ontvang nie indien:
  - jou baba vroeggebore is;

- jou baba pasgebore is (tot 28 dae oud) en sekere bloedprobleme of geelsug het (geel verkleuring van die vel of die oogwitte), of as hy/sy 'n produk wat kalsium bevat deur die are moet ontvang.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat CEFTRIAXONE FKSA aan jou gegee word:

- indien jy 'n kombinasie van die volgende simptome ervaar of voorheen ervaar het: uitslag, rooi vel, blase op die lippe, oë en mond, afskilferende vel, hoë koors, griepagtige simptome, verhoogde vlakke van lewerensieme waargeneem met bloedtoetse, en 'n toename in 'n sekere tipe witbloedsel (eosinofilie) en vergrote limfkliere (tekens van ernstige velreaksies, sien ook afdeling 4 “Moontlike newe-effekte”).
- indien jy onlangs produkte wat kalsium bevat ontvang het, of as dit binnekort aan jou toegedien gaan word;
- indien jy ander siektes het, soos hemolitiese anemie ('n vermindering in jou rooibloedselle wat jou vel liggeel kan maak en swakheid of kortasemheid kan veroorsaak);
- indien jy onlangs diarree gehad het nadat jy 'n antibiotikum ontvang het of as jy ooit probleme gehad het met jou derms (inflammasie van die derms);
- indien jy lewer- of nierprobleme het;
- indien jy galstene of nierstene het;
- indien jy op 'n lae-natriumdieet is.

<u>Indien jy 'n bloed- of urientoets benodig:</u>

Indien jy CEFTRIAXONE FKSA oor 'n lang tydperk ontvang moet jy dalk gereeld bloedtoetse laat doen. CEFTRIAXONE FKSA kan die uitslae van

urientoetse vir suiker en 'n bloedtoets, bekend as die Coombs-toets, beïnvloed. Die Coombs-toets kyk of daar antiliggame is wat aan jou rooibloedselle kan kleef en veroorsaak dat rooibloedselle te vroeg afsterf.

Lig die gesondheidsorgverskaffer wat die monster neem in dat CEFTRIAXONE FKSA aan jou gegee is.

Bejaardes (65 jaar en ouer)

Ensefalopatie (breinsiekte) is aangemeld met die gebruik van keftriaksoon, soos in CEFTRIAXONE FKSA (sien afdeling 4 “Moontlike newe-effekte”), veral by bejaarde pasiënte met baie swak nierfunksie of sentrale senuweestelselversteurings. Indien jy 'n veranderde geestestoestand, spiertrekkings en toevalle ervaar, praat met jou dokter aangesien hy/sy dit mag oorweeg om jou behandeling met CEFTRIAXONE FKSA te staak.

Kinders

Praat met jou dokter, apteker of verpleegster voordat CEFTRIAXONE FKSA aan jou kind gegee word, as die kind onlangs 'n medisyne wat kalsium bevat binneaars ontvang het, of op die punt staan om dit te ontvang.

Ander medisyne en CEFTRIAXONE FKSA

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Effek van CEFTRIAXONE FKSA op ander medisyne:

Jou dokter sal weet dat keftriaksoon, soos in CEFTRIAXONE FKSA, nie gelyktydig met kalsiumbevattende binneaarse oplossings soos Ringer se laktaat gegee mag word nie. Keftriaksoon en kalsium kan in jou bloed verbind en 'n neerslag in jou bloed vorm, wat jou niere, longe of galblaas kan beskadig.

Lig jou dokter of apteker in as jy die volgende neem:

- 'n antibiotikum genaamd chlooramfenikol (gebruik vir die behandeling van infeksies, gewoonlik in die oog). Chlooramfenikol kan die doeltreffende werking van CEFTRIAXONE FKSA aantas.

Effek van CEFTRIAXONE FKSA op ander medisyne:

- warfarien ('n bloedverdunner). CEFTRIAXONE FKSA kan die verdunnende effek verhoog en die risiko van bloeding verhoog.

Effek van CEFTRIAXONE FKSA op laboratoriumtoetse:

Lig jou gesondheidsorgverskaffer in as jy diabetes het. CEFTRIAXONE FKSA kan die resultate van (nie-ensiematiese) urientoetse vir suiker wysig. Ander toetse moet moontlik gebruik word om jou diabetes te moniteer terwyl jy met CEFTRIAXONE FKSA behandel word.

Indien jy bloedtoetse laat doen, neem kennis dat CEFTRIAXONE FKSA die uitslae van sommige bloedtoetse (soos die Coombs-toets) kan verander.

Sorg dat jy die gesondheidsorgverskaffer inlig dat jy met CEFTRIAXONE FKSA behandel word wanneer jy vir enige bloedtoetse gaan.

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy CEFTRIAXONE FKSA ontvang.

Swangerskap:

Veiligheid tydens menslike swangerskap is nie vasgestel nie. Keftriaksoon kruis die plasentaskans. CEFTRIAXONE FKSA moet nie aan jou gegee word as jy swanger is nie.

Borsvoeding:

Keftriaksoon word in borsmelk uitgeskei. Jy moet nie jou baba borsvoed as jy CEFTRIAXONE FKSA moet gebruik nie. Indien jy nie wil ophou borsvoed nie, praat met jou dokter oor ander alternatiewe behandelings.

Bestuur en die gebruik van masjinerie

Jy kan duiselig raak as jy CEFTRIAXONE FKSA ontvang. Jy moet nie bestuur of masjinerie hanteer voordat jy nie weet hoe CEFTRIAXONE FKSA jou aantas nie.

CEFTRIAXONE FKSA bevat natrium

CEFTRIAXONE FKSA bevat natrium.

Lig jou dokter in as natrium in jou dieet beperk moet word.

3. HOE OM CEFTRIAXONE FKSA TE GEBRUIK

Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.

Daar sal nie van jou verwag word om CEFTRIAXONE FKSA aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.

CEFTRIAXONE FKSA kan soos volg toegedien word:

- 'n drup (intraveneuse infusie) of as 'n inspuiting direk in 'n aar;
- in 'n spier.

CEFTRIAXONE FKSA oplossing word deur jou gesondheidsorgverskaffer voorberei en sal nie met kalsiumbevattende inspuitings gemeng word of gelyktydig daarmee aan jou gegee word nie.

Die gewone dosis is:

Jou dokter sal besluit wat die regte dosis van CEFTRIAXONE FKSA vir jou is. Die dosis sal afhang van die tipe infeksie en hoe ernstig die infeksie is, wat jy weeg en hoe goed jou niere en lewer werk. Die aantal dae of weke wat CEFTRIAXONE FKSA aan jou gegee word, sal afhang van die tipe infeksie wat jy het.

Volwassenes, ouer mense en kinders van 12 jaar en ouer met 'n liggaamsgewig van meer as of gelyk aan 50 kilogram (kg):

- 1 tot 2 g een keer per dag, afhangende van die erns en tipe infeksie.

Pasgebore babas, babas en kinders van 15 dae tot 12 jaar met 'n liggaamsgewig van minder as 50 kg:

- 20 - 80 mg CEFTRIAXONE FKSA vir elke kg liggaamsgewig van die kind een keer per dag, afhangende van die erns en tipe infeksie.
- Kinders met 'n liggaamsgewig van 50 kg of meer moet die gewone dosis vir volwassenes kry.

Pasgebore babas (0-14 dae):

- 20 - 50 mg CEFTRIAXONE FKSA vir elke kg liggaamsgewig van die kind een keer per dag, afhangende van die erns en tipe infeksie.

Mense met lewer- en nierprobleme:

- Jou dosis kan verskil van die gewone dosis. Jou dokter sal besluit hoeveel CEFTRIAXONE FKSA jy benodig, en sal jou noukeurig opvolg, afhangende van die erns van die lewer- en niersiekte.

Indien jy meer CEFTRIAXONE FKSA gebruik het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer CEFTRIAXONE FKSA sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering hanteer.

In die onwaarskynlike geval van 'n oordosis, kan jy naarheid, braking en diarree ontwikkel.

Indien jy vergeet om CEFTRIAXONE FKSA te gebruik

Aangesien 'n gesondheidsorgverskaffer CEFTRIAXONE FKSA sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

Indien jy ophou om CEFTRIAXONE FKSA te gebruik

Dit is belangrik dat jy die hele voorgeskrewe kursus ontvang. Dit moet nie onderbreek word net omdat jy weer beter voel nie. As die behandeling te vroeg gestaak word, kan die infeksie weer opflikker.

4. MOONTLIKE NEWE-EFFEKTE

CEFTRIAXONE FKSA kan newe-effekte hê.

Nie alle newe-effekte wat vir CEFTRIAXONE FKSA aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy CEFTRIAXONE FKSA ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, lig jou dokter dadelik in:

- **Erge allergiese reaksies**: sommige tekens kan 'n skielike swelling in die gesig, keel, lippe of mond wees (dit kan dit moeilik maak vir jou om asem te haal of te sluk), skielike swelling van hande, voete en enkels.
- **Borskaspyn** as onderdeel van allergiese reaksies, wat 'n simptoom kan wees van 'n hartaanval wat veroorsaak word deur 'n allergie (Kounis-sindroom).
- **Erge allergiese velreaksies**: sommige tekens is 'n ernstige uitslag wat vinnig ontwikkel, met blase of afskilfering van die vel en moontlik blase in

die mond (Stevens Johnson sindroom en toksiese epidermale nekrolise, ook bekend as SJS en TEN).

- 'n Kombinasie van enige van die volgende simptome: wydverspreide uitslag, hoë liggaamstemperatuur, verhoogde lewerensieme, bloedafwykings (eosinofilie), vergrote limfkliere en ander liggaamsorgane (geneesmiddelreaksie met eosinofilie en sistemiese simptome, ook bekend as "DRESS", of geneesmiddel-hipersensitiwiteitsindroom).

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige reaksie op CEFTRIAXONE FKSA gehad het. Jy kan dringende mediese aandag benodig.

Lig jou dokter dadelik in as jy enige van die volgende waarneem:

- Jarisch-Herxheimer-reaksie wat koors, kouekoors, hoofpyn, spierpyn en veluitslag, wat gewoonlik selfbeperkend is, veroorsaak. Dit vind plaas kort nadat behandeling met CEFTRIAXONE FKSA vir infeksies met spirochete soos Lyme-siekte begin is.
- 'n Breinsiekte (ensefalopatie), veral by bejaarde pasiënte. Sommige tekens kan wees veranderde verstandelike werking, spiertrekkings en toevalle.
- Waterige diarree wat lank aanhou of bloederig is, met maagpyn of koors. Dit kan 'n teken wees van 'n ernstige dermontsteking (kolitis, pseudomembraneuse kolitis) wat na die inname van antibiotika kan voorkom.
- Ontsteking van die pankreas (pankreatitis). Die tekens sluit in erge pyn in die maag wat na jou rug versprei, naarheid en braking.

Al hierdie newe-effekte is ernstig. Jy kan dringende mediese aandag benodig.

Ander newe-effekte

Gereelde newe-effekte

- Afwykings in jou witbloedselle (soos afname in leukosiete en toename in eosinofiele) en bloedplaatjies (afname in trombosiete).
- Los stoelgange of diarree.
- Veranderings in die bloedtoetsresultate vir lewerfunksie.
- Uitslag.

Minder gereeld

- Swaminfeksies (byvoorbeeld sproei).
- 'n Afname in die aantal witbloedselle (granulositopenie).
- 'n Afname in die aantal rooibloedselle (anemie).
- Probleme met die manier waarop jou bloed stol. Die tekens kan maklike kneusing, en pyn en swelling van die gewrigte insluit.
- Hoofpyn.
- Duiseligheid.
- Moeilike asemhaling (brongospasma).
- Voel naar of bring op.
- Pruritus (jeukerigheid).
- 'n Knopperige uitslag (netelroos) wat jou liggaam grotendeels kan bedek, jeukerigheid en swelling.
- Bloed of suiker in jou urien.
- Pyn of 'n brandgevoel langs die aar waar CEFTRIAXONE FKSA toegedien was. Pyn waar die inspuiting gegee was.
- 'n Hoë temperatuur (koors).

- Koue rillings.
- Edeem (opbou van vloeistof).
- Abnormale nierfunksietoetse (toename in bloedkreatinien).

Onbekende frekwensie (frekwensie kan nie uit die beskikbare gegewens geskat word nie)

- 'n Sekondêre infeksie wat moontlik nie reageer op die antibiotika wat voorheen voorgeskryf is nie.
- 'n Tipe bloedarmoede waar rooibloedselle vernietig word (hemolitiese anemie).
- Hematoom (erge kneusplek(ke)) of bloeding.
- Petegie (klein rooi of pers kolle wat deur bloeding in die vel veroorsaak word).
- Sweet.
- Gloede.
- Erge afname in witbloedselle (agranulositose).
- Stuiptrekkings.
- Vertigo (ronddraaiende gevoel).
- Ontsteking van die slymvlies in die mond (stomatitis).
- Inflammasie van die tong (glossitis). Die tekens sluit in swelling, rooi en seer tong.
- Probleme met jou galblaas en/of lewer, wat pyn, naarheid, braking, geel verkleuring van die vel, jeuk, buitengewoon donker urien en kleikleurige stoelgang kan veroorsaak.
- 'n Neurologiese toestand wat by pasgeborenes met ernstige geelsug (kernikterus) kan voorkom.

- Nierprobleme veroorsaak deur neerslag van kalsiumkeftriaksoon. Daar kan pyn wees tydens urinering of minder urien kan gevorm word.
- 'n Vals-positiewe resultaat in 'n Coombs-toets ('n toets vir sekere bloedafwykings).
- 'n Vals-positiewe resultaat vir galaktosemie ('n abnormale opbouing van die suiker, galaktose).
- CEFTRIAXONE FKSA kan sommige tipes bloedglukosetoetse beïnvloed - raadpleeg jou dokter.

Indien enige newe-effek ernstig raak, of indien jy enige newe-effek ondervind wat nie in hierdie inligtingsblad vermeld word nie, lig asseblief jou dokter, verpleegkundige of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van CEFTRIAXONE FKSA te verskaf.

Gesondheidsorgverskaffers word gevra om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com, en by die betrokke medisyne se regulatoriese owerheid in die land waarin die produk bemark word.

5. Hoe om CEFTRIAXONE FKSA te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 30 ºC. Hou die flessie of bottel in die karton om dit teen lig te beskerm.

Slegs vir eenmalige gebruik.

Chemiese en fisiese stabiliteit tydens gebruik van die hersaamgestelde produk is vir 12 uur by 25 °C en vir 2 dae by 2 - 8 °C aangetoon. Vanuit ’n mikrobiologiese oogpunt moet die produk dadelik gebruik word. Indien dit nie dadelik gebruik word nie, is die bergingstyd en toestande voor gebruik die verantwoordelikheid van die gebruiker en sal dit nie langer wees as die bogenoemde tye vir die chemiese en fisiese stabiliteit tydens gebruik nie.

Moenie hierdie medisyne na die vervaldatum gebruik wat op die kartonhouer en die flessie bottel se etiket na "Exp/Verv." aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie. Hierdie maatreëls sal help om die omgewing te beskerm.

6. Inhoud van die pakkie en ander inligting

Wat CEFTRIAXONE FKSA bevat

- Die aktiewe bestanddeel is keftriaksoon dinatriumhidraat.

Elke CEFTRIAXONE 500 mg FKSA flessie bevat 0,5 g keftriaksoon (as dinatriumhidraat).

Elke CEFTRIAXONE 1 g FKSA flessie bevat 1 g keftriaksoon (as dinatriumhidraat).

Elke CEFTRIAXONE 2 g FKSA flessie bevat 2 g keftriaksoon (as dinatriumhidraat).

- Daar is geen ander bestanddele teenwoordig nie.

Hoe CEFTRIAXONE FKSA lyk en inhoud van die pakkie

CEFTRIAXONE 500 mg FKSA: poeier vir oplossing vir inspuiting

CEFTRIAXONE 1 g FKSA: poeier vir oplossing vir inspuiting

CEFTRIAXONE 2 g FKSA: poeier vir oplossing vir infusie

'n Naaswit of gelerige, kristallyne poeier.

Die bereide oplossings is liggeel tot bruingeel.

Moenie CEFTRIAXONE FKSA gebruik as jy sien dat die oplossing nie helder is nie.

CEFTRIAXONE 500 mg FKSA: poeier vir oplossing vir inspuiting

15 mL glasflessie, kleurlose tipe-II-glasflessies, toegemaak met rubberproppe en afwipdekseltjies.

Pakke met 1; 10 of 25 enkeldosis flessies.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

CEFTRIAXONE 1 g FKSA: poeier vir oplossing vir inspuiting

15 mL glasflessie, kleurlose tipe-II-glasflessies, toegemaak met rubberproppe en afwipdekseltjie.

Pakke met 1; 10 of 25 enkeldosis flessies.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

CEFTRIAXONE 2 g FKSA: poeier vir oplossing vir infusie

15 mL glasflessie, kleurlose tipe-II-glasflessies, toegemaak met rubberproppe en afwipdekseltjies.

50 mL kleurlose tipe-II-glasbottels vir infusie, toegemaak met rubberproppe en afwipdekseltjies.

Verpakkings met 1 of 10 enkeldosis flessies of 1 enkeldosis-bottel.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikate

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Registrasienommers

CEFTRIAXONE 500 mg FKSA: 48/20.1.1/0227

CEFTRIAXONE 1 g FKSA: 48/20.1.1/0228

CEFTRIAXONE 2 g FKSA: 48/20.1.1/0229

Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.