PATIENT INFORMATION LEAFLET
SCHEDULING STATUS:

S4

OBKEF 250 mg INJECTION powder for injection
OBKEF 500 mg INJECTION powder for injection
OBKEF 1 g INJECTION powder for injection
Ceftriaxone
Sugar free

Read all of this leaflet carefully before you are given OBKEF.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- OBKEF 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 OBKEF is and what it is used for
OBKEF contains an antibiotic called ceftriaxone given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

2. What you need to know before you are given OBKEF
You must not be given OBKEF if:
- you are hypersensitive (allergic) to ceftriaxone, or any of the other ingredients of OBKEF (listed in section 6).
- you have previously had an allergic reaction to penicillin or to any other beta-lactams antibiotics (such as cephalosporins, carbapenems or monobactams; these are antibiotics used to treat infections). 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, and a severe rash that develops quickly.
- you are allergic to lidocaine (lignocaine) and you are to be given OBKEF as an injection into a muscle.
- it is mixed or administered simultaneously with intravenous calcium containing solutions or products, even via different infusion lines.

OBKEF must not be given to babies if:
- The baby is premature and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is to be given a product that contains calcium into their vein.
- The baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is to be given a product that contains calcium into their vein.

Warnings and precautions
Tell your doctor or healthcare provider before you are given OBKEF if you:
- have recently received or are about to receive products that contain calcium.
- have recently had diarrhoea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- have liver or kidney problems.
- have gall stones or kidney stones.
- 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).
- are on a low sodium diet.
- 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).

If you need a blood or urine test
If you are given OBKEF for a long time, you may need to have regular blood tests. OBKEF can affect the results of urine tests for sugar and a blood test known as the Coombs test. (The Coombs test will help your doctor determine if you have antibodies in your bloodstream that are causing your immune system to attack and destroy your own red blood cells). If you are having tests:
- Tell the person taking the sample that you have been given OBKEF.

Children
Talk to your doctor or pharmacist or nurse before your child is administered OBKEF if:
- He/she has recently been given or is to be given a product that contains calcium into their vein.

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes), when used together with OBKEF may reduce the effectiveness of one or the other medicine.
- Medicines known as Vitamin K antagonists (e.g., warfarin for blood thinning): OBKEF may enhance the blood thinning effect of Vitamin K antagonists and increase the risk for bleeding.
- Some products that may interact with OBKEF include calcium-containing IV fluids causing particles to form in the solution.
- OBKEF may interfere with certain laboratory tests (such as certain urine glucose tests), possibly causing false test results. Make sure laboratory personnel and all your doctors know you are using OBKEF.

Pregnancy and breastfeeding and fertility
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 taking OBKEF.
Safety in pregnant women and breastfeeding mothers has not been established.

Driving and using machines
OBKEF can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms. You should not drive or operate machines until you know how OBKEF affects you.

OBKEF contains:
OBKEF 250 mg INJECTION powder for solution for injection contains less than 1 mmol sodium (23 mg) per 250 mg vial, i.e. is essentially "sodium free".

OBKEF 500 mg INJECTION powder for solution for injection or infusion contains 42.7 mg sodium (main component of cooking/table salt) per 500 mg vial, equivalent to 2.15 % of the recommended maximum daily dietary intake of sodium for an adult.

OBKEF 1 g INJECTION powder for solution for injection or infusion contains 85.4 mg sodium (main component of cooking/table salt) per 1 g vial, equivalent to 4,3 % of the recommended maximum daily dietary intake of sodium for an adult.

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

OBKEF is usually given by a doctor or nurse. It can be given as:
- a drip (intravenous infusion) or as an injection directly into a vein or
- into a muscle.

OBKEF is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

The usual dose is:
Adults and children over 12 years and over:
- The usual dose is 1 to 2 g once a day. If you have a severe infection, your doctor will give you a higher dose (up to 4 g daily).

Newborn babies, infants and children upto 12 years:
Newborn babies (up to 14 days):
- The usual dose is 20 – 50 mg/kg bodyweight once daily.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

Infants and young children (15 days to 12 years):
- The usual dose is 20-80 mg OBKEF 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.
- Doses of more than 50 mg/kg body weight will be given by a drip over at least 30 minutes.

For treatment of bacterial meningitis (an infection of the membranes (meninges) surrounding the brain and spinal cord) in newborn babies, infants and children, your doctor will give a higher dose up to 100 mg for each kg of body weight to a maximum of 4 g once a day. For bacterial meningitis in adults, the recommended dose is 4 g daily.

For the treatment of gonorrhoea, your doctor will give you a single dose of 125 mg injection into a muscle.

To prevent an infection after surgery, a single dose of 1 to 2 g is given 30 to 90 minutes before the operation.

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

Your doctor will decide the correct dose of OBKEF for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given OBKEF depends on what sort of infection you have.

If you are given more OBKEF than you should
Since a healthcare provider will administer OBKEF, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take OBKEF
Since a healthcare provider will administer OBKEF, it is unlikely that the dose will be missed.

4. Possible side effects:
OBKEF can have side effects.
Not all side effects reported for OBKEF are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OBKEF, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking OBKEF and tell your doctor immediately:
- 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.

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

Tell your doctor immediately if you notice any of the following:
- 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).
- 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).
- Redness and peeling of the skin over large areas of the body.
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting OBKEF treatment for infections with spirochete such as Lyme disease.

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

Tell your doctor if you notice any of the following:

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 side effects
- 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.
- Severe bruising (hematoma) or bleeding.
- Headache.
- Dizziness.
- Feeling sick or being sick.
- Pruritis (itching).
- Itchy rash, tiny round, brown-purple spots due to bleeding under the skin, a rash of purple spots, a widely spread out rash.
- Sweating.
- Pain or a burning feeling along the vein where OBKEF has been given. Pain where the injection was given.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Difficulty in breathing (bronchospasm).
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- Blood or sugar in your urine.
- Oedema (fluid build-up).
- Shivering.

Frequency of side effects not known
- A secondary infection that may not respond to the antibiotic previously prescribed.
- Form of anaemia where red blood cells are destroyed (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.
- Inflammation of the mucus lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder, which may cause pain, feeling sick and being sick.
- 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).
- OBKEF may interfere with some types of blood glucose tests - please check with your doctor.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OBKEF.

5. How to store OBKEF
KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Store at or below 25 °C.
Protect from light.
Store in the original container.
Do not use OBKEF after the expiry date stated on the carton.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What OBKEF contains
The active substance in each vial is ceftriaxone sodium equivalent to 250 mg or 500 mg or 1 g ceftriaxone.
There are no other ingredients in this product.

What OBKEF looks like and contents of the pack
OBKEF 250 mg INJECTION powder for injection: A white to yellowish crystalline powder.

OBKEF 500 mg INJECTION powder for injection: A white to yellowish crystalline powder.

OBKEF 1 g INJECTION powder for injection: A white to yellowish crystalline powder.

They packed in USP type II 10 ml flint glass vial stoppered with 20 mm grey bromo butyl rubber stoppers and sealed with 20 mm orange flip-off Aluminium seal. Each vial is placed in a cardboard carton (1 x Vial).

Holder of Certificate of Registration
Oethmaan Biosims (Pty) Ltd
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Not applicable.

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OBKEF 1 g INJECTION powder for injection: 47/20.1.1/1245

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PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS:

S4

OBKEF 250 mg INSPUITING poeier vir inspuiting
OBKEF 500 mg INSPUITING poeier vir inspuiting
OBKEF 1 g INSPUITING poeier vir inspuiting
Seftriaksoon
Suikervry

Lees hierdie hele blad noukeurig deur voordat OBKEF aan u gegee word.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- OBKEF is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is

1. Wat OBKEF is en waarvoor dit gebruik word
OBKEF bevat 'n antibiotikum genaamd seftriaksoon wat aan volwassenes en kinders (insluitend pasgebore babas) gegee word. Dit werk deur bakterieë wat infeksies veroorsaak dood te maak. Dit behoort aan 'n groep medisyne wat sefalosporiene genoem word.

2. Wat u moet weet voordat u OBKEF kry
OBKEF moet nie aan u gegee word nie as:
- u hipersensitief (allergies) vir seftriaksoon of vir enige van die ander bestanddele van OBKEF (gelys in afdeling 6) is.
- u voorheen 'n allergiese reaksie op penisillien of op enige ander beta-laktaam-antibiotikum gehad het (soos sefalosporiene, karbapenems of monobaktame; dit is antibiotika wat gebruik word om infeksies te behandel). Die tekens is onder meer skielike swelling van die keel of gesig wat dit moeilik kan maak om asem te haal of te sluk, skielike swelling van die hande, voete en enkels, en 'n erge uitslag wat vinnig ontwikkel.
- u allergies vir lidokaïen (lignokaïen) is, moet OBKEF as 'n inspuiting in 'n spier gegee word.
- dit gemeng of gelyktydig met binneaarse kalsiumbevattende oplossings of produkte gegee word, selfs via verskillende infusielyne.

OBKEF moet nie aan babas gegee word nie as:
- die baba prematuur gebore is en sekere bloedprobleme of geelsug (geel verkleuring van die vel of die wit van die oë) het of 'n produk wat kalsium bevat in 'n aar moet kry.
- die baba pasgebore is (tot 28 dae oud) en sekere bloedprobleme of geelsug (geel verkleuring van die vel of die wit van die oë) het of 'n produk wat kalsium bevat in 'n aar moet kry.

Waarskuwings en voorsorgmaatreëls
Sê vir u dokter of gesondheidsorgverskaffer voordat u OBKEF kry as u:
- onlangs produkte wat kalsium bevat, ontvang het of gaan ontvang.
- onlangs diarree gehad het nadat u 'n antibiotikum gebruik het. U al ooit probleme met u ingewande gehad het, veral kolitis (ontsteking van die dikderm).
- lewer- of nierprobleme het.
- galstene of nierstene het.
- ander siektes het, soos hemolitiese anemie ('n daling in u rooibloedseltelling wat u vel liggeel kan maak en swakheid of uitasemheid kan veroorsaak).
- 'n dieet met min natrium volg.
- 'n kombinasie van enige van die volgende simptome ervaar of ervaar het: uitslag, rooi vel, blase op die lippe oë en mond, vel wat afdop, hoë koors, griepagtige simptome, hoë vlakke van lewerensieme wat in bloedtoetse gesien word, 'n toename in 'n tipe witbloedsel (eosinofilie) en vergrote limfknope (tekens van erge velreaksies, sien ook afdeling 4).

As u 'n bloed- of urientoets nodig het
As OBKEF vir 'n lang tyd aan u gegee word, moet u dalk gereelde bloedtoetse ondergaan. OBKEF kan die resultate van urientoetse vir suiker en 'n bloedtoets bekend as die Coombs-toets beïnvloed. (Die Coombs-toets sal u dokter help om te bepaal of u teenliggaampies in u bloedstroom het wat veroorsaak dat u immuunstelsel u eie rooibloedselle aanval en vernietig). As u toetse ondergaan:
- Sê vir die persoon wat die monster neem dat u OBKEF gekry het.

Kinders
Praat met u dokter, apteker of verpleegkundige voordat OBKEF aan u kind gegee word as:
- Hy/sy het onlangs 'n produk wat kalsium bevat in 'n aar gekry het of gaan kry.

Ander medisyne en OBKEF
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).
Sê veral vir u dokter of apteker indien u enige van die volgende middels gebruik:
- 'n Antibiotikum genaamd chlooramfenikol (wat gebruik word om infeksies te behandel, veral van die oë) kan, wanneer dit saam met OBKEF gebruik word, die doeltreffendheid van die een of die ander middel verlaag.
- Medisyne bekend as vitamien K-antagoniste (bv. warfarien wat bloed dun maak): OBKEF kan die effek van Vitamien K-antagoniste om bloed dun te maak versterk en die risiko vir bloeding verhoog.
- Van die produkte wat interaksie met OBKEF kan hê, is onder meer kalsiumbevattende IV-vloeistowwe wat veroorsaak dat deeltjies in die oplossing vorm.
- OBKEF kan inmeng met sekere laboratoriumtoetse (soos sekere urientoetse vir glukose), wat moontlik vals toetsresultate veroorsaak. Maak seker dat laboratoriumpersoneel en al u dokters weet dat u OBKEF gebruik.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u OBKEF kry.

Die veiligheid vir swanger en borsvoedende moeders is nie bepaal nie.

Motorbestuur en gebruik van masjinerie
OBKEF kan duiseligheid veroorsaak. As u duiselig voel, moet u nie 'n voertuig bestuur of enige gereedskap of masjiene gebruik nie. Praat met u dokter as u hierdie simptome ervaar. U moet nie 'n voertuig bestuur of masjinerie hanteer nie totdat u weet hoe OBKEF u affekteer.

OBKEF bevat:
OBKEF 250 mg INSPUITING poeier vir oplossing vir inspuiting bevat minder as 1 mmol natrium (23 mg) per 250 mg flessie, en is dus in wese "natriumvry".
OBKEF 500 mg INSPUITING poeier vir oplossing vir inspuiting of infusie bevat 42,7 mg natrium (hoofkomponent van kook/tafelsout) per 500 mg flessie, gelykstaande aan 2,15 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.
OBKEF 1 g INSPUITING poeier vir oplossing vir inspuiting of infusie bevat 85,4 mg natrium (hoofkomponent van kook/tafelsout) per 1 g flessie, gelykstaande aan 4,3 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

3. Hoe om OBKEF te gee
Dit sal nie van u verwag word om OBKEF aan uself te gee nie. Dit sal aan u gegee word deur 'n persoon wat gekwalifiseerd is om dit te doen.
OBKEF word gewoonlik deur 'n dokter of verpleegkundige gegee. Dit kan gegee word as:
- 'n drup (binneaarse infusie) of as 'n inspuiting direk in 'n aar of
- in 'n spier.

OBKEF word deur die dokter, apteker of verpleegkundige aangemaak en sal nie met kalsiumbevattende inspuitings gemeng of aan u gegee word nie.

Die gewone dosis is:
Volwassenes en kinders ouer as 12 jaar:
- Die gewone dosis is 1 tot 2 g een keer per dag. As u 'n erge infeksie het, sal u dokter 'n hoër dosis vir u gee (tot 4 g daagliks).

Pasgebore babas, babas en kinders tot 12 jaar:
Pasgebore babas (tot 14 dae):
- Die gewone dosis is 20 – 50 mg/kg liggaamsgewig een keer per dag.
- Die maksimum daaglikse dosis moet nie meer as 50 mg vir elke kg van die baba se gewig wees nie.

Babas en kinders (15 dae tot 12 jaar):
- Die gewone dosis is 20-80 mg OBKEF vir elke kg van die kind se liggaamsgewig een keer per dag, afhangende van die erns en tipe infeksie.
- Kinders met 'n liggaamsgewig van 50 kg of meer moet die gewone volwasse dosis kry.
- Dosisse van meer as 50 mg/kg liggaamsmassa moet per infusie oor ten minste 30 minute gegee word.

Vir die behandeling van bakteriële meningitis ('n infeksie van die membrane (meninges) rondom die brein en rugmurg) in pasgebore babas, babas en kinders, sal u dokter 'n hoër dosis van tot 100 mg vir elke kg liggaamsgewig tot 'n maksimum van 4 g een keer per dag gee. Vir bakteriële meningitis in volwassenes is die aanbevole dosis 4 g een keer per dag.

Vir die behandeling van gonorree sal u dokter vir u 'n enkele dosis van 125 mg as inspuiting in 'n spier gee.

Om 'n infeksie na 'n operasie te voorkom, word 'n enkele dosis van 1 tot 2 g 30 tot 90 minute voor die operasie gegee.

Mense met lewer- en nierprobleme
U kan 'n ander dosis as die gewone dosis kry. U dokter sal besluit hoeveel OBKEF u nodig het en sal u noukeurig nagaan, afhangende van die erns van die lewer- en niersiekte.
U dokter sal die korrekte dosis van OBKEF vir u bepaal. Die dosis sal afhang van die erns en tipe infeksie, of u enige ander antibiotika gebruik, u gewig en ouderdom en hoe goed u niere en lewer werk. Die aantal dae of weke wat u OBKEF kry, hang af van watter soort infeksie u het.

As u meer OBKEF gekry het as wat u moes
Omdat 'n gesondheidsorgverskaffer OBKEF sal toedien, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

As u vergeet om OBKEF te kry
Aangesien 'n gesondheidsorgverskaffer OBKEF sal gee, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte:
OBKEF kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir OBKEF aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe-effekte ervaar terwyl u OBKEF kry, moet u u dokter, apteker of ander gesondheidspraktisyn asseblief om advies raadpleeg.
Indien enige van die volgende voorkom, moet u ophou om OBKEF te gebruik en dadelik vir u dokter daarvan sê:
- Skielike swelling van die gesig, keel, lippe of mond. Dit kan dit moeilik maak om asem te haal of te sluk.
- Skielike swelling van die hande, voete of enkels.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige reaksie op OBKEF gehad het. Dit mag wees dat u dringende mediese aandag nodig het.

Sê dadelik vir u dokter as u enige van die volgende opmerk:
- Erge uitslag wat vinnig ontwikkel, met blase of afskilfering van die vel en moontlik blase in die mond (Stevens-Johnsonsindroom en toksiese epidermale nekrolise).
- 'n Kombinasie van die volgende simptome: wydverspreide veluitslag, hoë liggaamstemperatuur, hoër vlakke lewerensieme, bloedabnormaliteite (eosinofilie), vergrote limfkliere en betrokkenheid van ander liggaamsorgane (geneesmiddelreaksie met eosinofilie en sistemiese simptome ook bekend as GRESS of die sindroom van hipersensitiwiteit vir geneesmiddels).
- Rooiheid en afskilfering van die vel oor groot dele van die liggaam.
- Jarisch-Herxheimerreaksie wat koors, kouekoors, hoofpyn, spierpyn en veluitslag veroorsaak wat gewoonlik selfbeperkend is. Dit kom voor kort nadat met behandeling met OBKEF vir infeksies met spirogete soos Lyme se siekte begin is.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom
- Abnormaliteite in u witbloedselle (soos 'n afname in die aantal leukosiete en 'n toename in eosinofiele) en bloedplaatjies (afname in trombosiete).
- Los stoelgang en diarree.
- Veranderings in die uitslae van bloedtoetse van nier- en lewerfunksie.
- Veluitslag.

Newe-effekte wat minder dikwels voorkom
- Fungusinfeksies (byvoorbeeld sproei).
- 'n Daling in die aantal witbloedselle (granulositopenie).
- 'n Afname in die aantal roobloedselle (anemie).
- Probleme met die manier waarop u bloed stol. Die tekens kan maklike kneusing en pyn en swelling in die gewrigte insluit.
- Erge kneusing (hematoom) of bloeding.
- Hoofpyn.
- Duiseligheid.
- Naarheid of braking.
- Pruritus (jeuk).
- Jeukende uitslag, klein ronde, bruinpers kolle as gevolg van bloeding onder die vel, 'n uitslag van pers kolle, 'n wydverspreide uitslag.
- Sweet.
- Pyn of 'n brandende gevoel in die aar waar OBKEF gegee is. Pyn waar die inspuiting gegee is.
- Hoë temperatuur (koors).
- Abnormale uitslae van lewerfunksietoetse (meer kreatinien in die bloed).
- Inflammasie van die dikderm (kolon). Die tekens sluit in diarree, gewoonlik met bloed en slym, maagpyn en koors.
- Probleme met asemhaling (brongospasma).
- 'n Knopperige uitslag (galbulte) wat 'n groot deel van die liggaam kan bedek, jeukerig voel en swel.
- Bloed of suiker in die urien.
- Edeem (opbou van vloeistof).
- Bewerasie.

Newe-effekte met onbekende frekwensie
- 'n Sekondêre infeksie wat dalk nie reageer op die antibiotika wat voorheen voorgeskryf is nie.
- 'n Vorm van anemie waar roobloedselle vernietig word (hemolitiese anemie).
- Daling in die aantal witbloedselle (agranulositose).
- Stuiptrekkings.
- Vertigo (sensasie van in die rondte draai).
- Ontsteking van die pankreas (pankreatitis). Die tekens is onder meer erge pyn in die maag wat na die rug versprei.
- Ontsteking van die slymvlies van die mond (stomatitis).
- Ontsteking van die tong (glossitis). Die tekens is onder meer swelling, rooiheid en seerheid van die tong.
- Probleme met die galblaas, wat pyn, naarheid en braking kan veroorsaak.
- 'n Neurologiese toestand wat in pasgeborenes met erge geelsug kan voorkom (kernikterus).
- Nierprobleme wat veroorsaak word deur afsettings van kalsiumseftriaksoon. Daar kan pyn tydens urinering of 'n lae uitset van urien wees.
- 'n Vals positiewe uitslag van 'n Coombs-toets ('n toets vir sekere bloedprobleme).
- 'n Vals positiewe uitslag vir galaktosemie (abnormale opbou van suiker galaktose).
- OBKEF kan sekere soorte bloedglukosetoetse beïnvloed - raadpleeg u dokter asseblief.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by SAROGP ("SAHPRA") aanmeld via die vorm "6.04 Adverse Drug Reaction Reporting Form" wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van OBKEF te gee.

5. Hoe om OBKEF te bêre
HOU BUITE BEREIK EN SIG VAN KINDERS.
Bêre by of onder 25 ºC.
Beskerm teen lig.
Bêre in die oorspronklike houer.
Moet OBKEF na die vervaldatum op die karton gebruik nie.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting
Wat OBKEF bevat
Die aktiewe bestanddeel in elke flessie is natriumseftriaksoon gelykstaande aan 250 mg of 500 mg of 1 g seftriaksoon.
Daar is geen ander bestanddele in hierdie produk nie.

Hoe OBKEF lyk en die inhoud van die pakkie
OBKEF 250 mg INSPUITING poeier vir inspuiting: 'n Wit tot gelerige kristallyne poeier.

OBKEF 500 mg INSPUITING poeier vir inspuiting: 'n Wit tot gelerige kristallyne poeier.

OBKEF 1 g INSPUITING poeier vir inspuiting: 'n Wit tot gelerige kristallyne poeier.

Hulle is verpak in flessies van USP tipe II-flintglas van 10 ml met grys broombutielrubberproppe van 20 mm en is verseël met oranje afwipaluminiumseëls van 20 mm. Elke flessie is in 'n karton verpak (1 x flessie).

Houer van registrasiesertifikaat
Oethmaan Biosims (Pty) Ltd
Sherwood House 207A
Greenacres Kantoorpark
h/v Victory- en Rustenburgweg
Victory Park
Johannesburg

Hierdie blad is laas hersien in
Nie toepaslik nie

Registrasienommer
OBKEF 250 mg INSPUITING poeier vir inspuiting: 49/20.1.1/0416

OBKEF 500 mg INSPUITING poeier vir inspuiting: 49/20.1.1/0417

OBKEF 1 g INSPUITING poeier vir inspuiting: 47/20.1.1/1245

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