PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

OBKEF 250 mg INJECTION powder for injection

OBKEF 500 mg INJECTION powder for injection

OBKEF 1 g INJCTION 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

2. What you need to know before you take OBKEF

3. How to take OBKEF

4. Possible side effects

5. How to store OBKEF

6. Contents of the pack and other information

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

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Not applicable.

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