Approved Patient Information Leaflet for Medicines for Human Use

SCHEDULING STATUS: S4

KOCEF-250; KOCEF-500; KOCEF-1000 (injection)

Ceftriaxone sodium

Sugar free

Read all of this leaflet carefully before you are given KOCEF

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

What is in this leaflet

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

1. What KOCEF is and what it is used for

KOCEF contains ceftriaxone sodium which is an antibiotic belonging to a group of antibiotic medicines called cephalosporins. KOCEF is used for the treatment of infections caused by bacteria. It is also used prior to some surgical operations to reduce the risk of bacterial infections.

2. What you need to know before you are given KOCEF

KOCEF should not be administered to you

- if you are hypersensitive (allergic) to ceftriaxone or to other medicines containing related antibiotics such as cephalosporins or penicillins
- if KOCEF is mixed together with calcium-containing solutions or products, or if KOCEF is going to be administered to you through an intravenous infusion line which contains calcium-containing fluid, it could cause a precipitation of ceftriaxone-calcium salt
- if you have had a bad reaction to a lidocaine/lignocaine injection in the past.

KOCEF should not be administered to babies

- if the baby is premature
- the baby is newborn (up to 28 days) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is about to be given another injection that contains calcium.

Warnings and precautions

Tell your doctor or health care provider before being given KOCEF or while being given KOCEF if

- you have recently received or are about to receive calcium
- you develop a severe diarrhoea or if you have ever had problems with your gut, in particular colitis (inflammation of the bowel)
- you have liver and kidney problems (see section 4)
- you have gall stones or kidney stones

- 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)
- you are on a low sodium diet
- you experience a change in mental state, fits, or sudden jerks
- 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”).

Children

Talk to your doctor or nurse before your child is administered KOCEF if:

- Your child has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and KOCEF

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

- KOCEF should not be added to solutions containing calcium
- if you are taking medicine to reduce the clotting of your blood, tell your doctor before you receive KOCEF
- if you are taking a medicine containing chloramphenicol (an

antibiotic used to treat infections, particularly of the eyes), tell your doctor before you receive KOCEF.

If you need a blood or urine test

If you are given KOCEF for a long time, you may need to have regular blood tests.

KOCEF can affect the results of urine tests for sugar and a blood test known as the Coombs test.

If you are having tests:

- Tell the person taking the sample that you have been given KOCEF.
- If you are diabetic or need to have your blood glucose level monitored, you should not use certain blood glucose monitoring systems which may estimate blood glucose incorrectly while you are receiving ceftriaxone. If you use such systems check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary.

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 health care provider for advice before taking KOCEF.

Safety and efficacy have not been established. You should not receive KOCEF when you are pregnant or breastfeeding your baby.

Driving and using machines

KOCEF can cause drowsiness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

KOCEF contains sodium

Each KOCEF 250 mg vial contains less than 1 mmol sodium (23 mg) per 250 mg vial, i.e. is essentially “sodium free”.

Each KOCEF 500 mg vial contains approximately 41,5 mg of sodium per 500 mg vial, equivalent to 2,08 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Each KOCEF 1000 mg vial contains approximately 83 mg of sodium per 1 g vial, equivalent to 4,15 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How KOCEF is given

The usual dosage for adults and children over 12 years is 1 — 2 g of KOCEF once daily. The dosage could be raised by your doctor depending on the severity of the disease, your bodyweight, your age and your individual response to KOCEF.

The dose for newborn babies (up to 14 days) is calculated by your doctor according to the body weight of the baby. A similar calculation is done for infants (15 days and older) and children up to 12 years.

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

Duration of administration

Your doctor will tell you how long your treatment with KOCEF will last.

If you have the impression that the effect of KOCEF is too strong or too weak, tell your doctor or pharmacist.

Method of administration

KOCEF will be injected in a muscle or directly in a vein. You will not be expected to give yourself KOCEF. It will be given to you by a person who is qualified to do so.

If you are given more KOCEF than you should

Since a health care provider will administer KOCEF, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you did not get your dose of KOCEF

Since a health care provider will administer KOCEF, it is unlikely that the dose will be missed.

Effects when treatment with KOCEF is stopped

The duration of KOCEF therapy varies, depending on the nature of your illness and your individual response to the treatment.
You will receive KOCEF for at least 2 - 3 days after starting to recover from your illness or after a surgical operation to prevent infections from occurring.

4. Possible side effects

KOCEF can have side effects.

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

If any of the following happens, while or after receiving KOCEF, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- fainting
- 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).
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting KOCEF treatment for infections caused by spirochetes such as Lyme disease.

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

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

- diarrhoea, usually with blood and mucus, stomach pain and fever, these may be signs of inflammation of the large intestine (colitis)
- signs of recurrent infections such as fever or sore throat
- problems with the gallbladder and/or liver, which may cause pain, nausea, vomiting, yellowing of the skin, itching, unusually dark urine and clay-coloured stools
- progressive loss of memory and ability to think, subtle personality changes, inability to concentrate, feeling extremely tired, and progressive loss of consciousness, these may be signs of encephalopathy
- convulsions (fits)
- kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine
- inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.

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 function
- rash.

Less frequent side effects:

- fungal infections affecting the genital regions (e.g. 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
- feeling sick or being sick.
- difficulty in breathing (bronchospasm)
- pruritis (itching) or urticaria (hives)
- fever, shivering, pain or a burning feeling along the vein where the injection has been given, pain where the injection was given, oedema (fluid build-up)
- abnormal kidney function test (blood creatinine increased)
- sugar in your urine (seen on a urine test)

Side effects with frequency unknown:

- secondary infection
- vertigo (spinning sensation).
- 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)
- 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). KOCEF 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, 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 KOCEF**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store KOCEF

Store all medicines out of reach of children

Store at or below 25 °C.

Protect from light.

Storage directions for reconstituted product:

Store for up to 6 hours at 25 °C or 24 hours at 2 - 8 °C (in a refrigerator).

Do not freeze the reconstituted product.

The doctor or nurse who is administering KOCEF to you, will make sure that the medicine is not used after the expiry date printed on the vial.

6. Contents of the pack and other information

What KOCEF contains

- The active substance is ceftriaxone sodium. There are no other ingredients.

What [PRODUCT NAME] looks like and contents of the pack

KOCEF-250, KOCEF-500, KOCEF-1000 powder for injection is a sterile, white to yellowish-orange powder supplied in clear glass vials. The reconstituted solution is pale yellow to amber in colour.

KOCEF-250 is supplied in a 10 mL clear glass vial with grey bromo butyl stopper and aluminium flip off seal with green plastic top, containing powder equivalent to 250 mg ceftriaxone for reconstitution. Vials are supplied in cartons containing singles.

KOCEF-500 is supplied in a 10 mL clear glass vial with grey bromo butyl stopper and aluminium flip off seal with light blue plastic top, containing powder equivalent to 500 mg ceftriaxone for reconstitution. Vials are supplied in cartons containing singles.

KOCEF-1000 is supplied in a 15 mL clear glass vial with grey bromo butyl stopper and aluminium flip off seal with grey plastic top, containing powder equivalent to 1 g ceftriaxone for reconstitution. Vials are supplied in cartons containing singles.

Holder of Certificate of Registration

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