PROPOSED PATIENT INFORMATION LEAFLET - CLEAN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

SEFTRY 0,5 powder for solution for injection

SEFTRY 1,0 powder for solution for injection

SEFTRY 2,0 powder for solution for injection

Ceftriaxone

Sugar free

Read all of this leaflet carefully before you are given SEFTRY.

- 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.
- SEFTRY 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 SEFTRY is and what it is used for

2. What you need to know before you use SEFTRY

3. How to use SEFTRY

4. Possible side effects

5. How to store SEFTRY

6. Contents of the pack and other information

1. What SEFTRY is and what it is used for

SEFTRY is an antibiotic used to treat infections in different parts of the body, caused by bacteria.

Ceftriaxone is also used to prevent infections following surgery.

Ceftriaxone will not work against infections caused by viruses such as colds or the flu.

Ceftriaxone belongs to a group of antibiotics called cephalosporins These antibiotics work by killing the bacteria that are causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

You should not receive SEFTRY:

- if you have an allergy to ceftriaxone, or any other cephalosporins or any of the other ingredients of SEFTRY (listed in section 6).

  Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.
- if you have had a serious allergic reaction to any penicillins or to any other beta-lactams antibiotics (such as cephalosporins, carbapenems or monobactams; these are antibiotics used to treat infections).

  You may be more likely to have an allergic reaction to SEFTRY if you are allergic to penicillin medicines.
- if you are allergic to lidocaine (lignocaine) and you are to be given SEFTRY as an injection into a muscle.

- if it is mixed or administered simultaneously with intravenous calcium containing solutions or products, even via different infusion lines.

SEFTRY 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.

If you are not sure whether you should be given SEFTRY. Tell your doctor, nurse or pharmacist.

Warnings and precautions

Special care to be taken with SEFTRY:

Before using SEFTRY, tell your doctor -

- if you have had any type of allergic reaction to any cephalosporin or penicillin medicines.
- if you are allergic to lignocaine or other local anaesthetics. Lignocaine can be mixed with SEFTRY prior to injection.
- if you have allergies to:
    - any other medicines
    - any other substances, such as foods, preservatives or dyes
- if you have, or have had any medical conditions, including:
    - kidney disease
    - stomach or bowel problems
    - liver disease
    - bleeding problems

- have recently received or are about to receive products that contain calcium.
- 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).
- Children

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

Severe allergic reactions

Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome (also known as allergic angina), which can cause chest pain, shortness of breath, or a fast or irregular heartbeat.

Diarrhoea

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after SEFTRY has been stopped. Do not take any diarrhoea medicine without first checking with your doctor. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Fungal infections

If you get a sore white mouth or tongue while being given or soon after stopping SEFTRY, tell your doctor or pharmacist. Also tell your doctor or pharmacist if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of ceftriaxone allows fungi to grow and the above symptoms to occur. SEFTRY does not work against fungi.

Elderly (65 years and older)

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

Laboratory tests:

If you have to test your urine for sugar while you are being given SEFTRY, make sure your doctor knows which type of test you use. SEFTRY may affect the results of some of these tests.

If you have to have any blood tests, tell your doctor you are being given this medicine. SEFTRY may affect the results of some blood tests.

Other medicines and SEFTRY

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:

Effect of SEFTRY on other medicines:

- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes), when used together with SEFTRY may reduce the effectiveness of one or the other medicine.
- Medicines known as Vitamin K antagonists (e.g., warfarin for blood thinning): SEFTRY may enhance the blood thinning effect of Vitamin K antagonists and increase the risk for bleeding.
- Some products that may interact with SEFTRY include calcium-containing IV fluids causing particles to form in the blood which may damage your kidneys, lungs, or gallbladder.
- SEFTRY 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 SEFTRY.

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 SEFTRY.

Pregnancy:

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

Breastfeeding:

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

Driving and using machines

SEFTRY may cause dizziness in some people. Make sure you know how you react to SEFTRY before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

SEFTRY contains:

SEFTRY 0.5 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.
SEFTRY 1,0 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.
SEFTRY 2,0 contains 170.8 mg sodium (main component of cooking/table salt) per 2 g vial, equivalent to 8.6 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use SEFTRY

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

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

SEFTRY must only be given by a doctor or nurse.

SEFTRY can be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle

Your doctor will decide what dose and how long you will receive SEFTRY. This depends on your condition and whether you are taking any other medicines. For most infections, SEFTRY is usually given once a day. If you have the impression that the effect of SEFTRY is too strong or too weak, talk to your doctor or pharmacist.

The length of treatment is usually between 4 days and 2 weeks.

Sometimes only a single dose of SEFTRY is required for the treatment and prevention of certain infections.

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 SEFTRY 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 infants and children, your doctor will give a 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 250 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 SEFTRY 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 SEFTRY 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 SEFTRY depends on what sort of infection you have.

If you are given more SEFTRY than you should

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

If you forget to take SEFTRY

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

If you stop using SEFTRY

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:

SEFTRY can have side effects.

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

If any of the following happens, stop using SEFTRY 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.
- Severe allergic reactions which may include difficulty breathing, swelling of the face, lips, tongue, or throat, rash, itching, or hives. These reactions can sometimes lead to a heart problem called Kounis syndrome, which can cause chest pain, shortness of breath, or a fast or irregular heartbeat.

These are all very serious side effects. If you have them, you may have had a serious reaction to SEFTRY. 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 SEFTRY 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.
- Severe skin reactions, including Linear IgA. Symptoms can include itchy or painful blisters, often in a line or cluster, and areas of raw or denuded skin.

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).
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- 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.
- A brain disorder (encephalopathy)
- Difficulty in breathing (bronchospasm).
- Nausea, vomiting.
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- 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.
- Blood or sugar in your urine.
- Sweating.
- Pain or a burning feeling along the vein where SEFTRY has been given. Pain where the injection was given.
- A high temperature (fever), oedema (fluid build-up), shivering.
- Abnormal kidney function test (blood creatinine increased).

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).
- Abnormal bruising or bleeding (haematoma)
- Abnormal blood clotting test results
- Allergic (hypersensitivity reactions)
- Convulsions.
- Vertigo (spinning sensation).
- Kounis syndrome (heart problems due to severe allergic reaction)

- 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).
- Inflammation of the liver.
- Serious skin reactions, tiny round, brown-purple spots due to bleeding under the skin, sweating, flushing
- 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).
- SEFTRY 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 SEFTRY.

5. HOW TO STORE SEFTRY

Store all medicines out of reach of children.

Store below 25 °C in the outer carton to protect the medicine from light.

The reconstituted solution is intended for immediate use, but the solution may be stored in the original vials in the refrigerator at 2 °C to 8 °C for 48 hours or below 25 °C for 24 hours. Keep the container in the outer carton in order to protect from light.

Do not freeze.

Do not use SEFTRY if you notice:

- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SEFTRY contains

The active substance in each vial is ceftriaxone sodium equivalent to 500 mg or 1 g or 2 g ceftriaxone.

There are no other ingredients in this product.

What SEFTRY looks like and contents of the pack

SEFTRY 0,5 Powder for solution for injection:

White to yellowish powder in a 10 or 15 ml injection vial made of colourless glass, with a grey rubber stopper and aluminium cap with a colourless flip-off seal.

SEFTRY 1,0 Powder for solution for injection:

White to yellowish powder in a 10 ml colourless vial, closed with grey rubber stoppers, the stoppers are fixed with aluminium rings. The vials are capped with a green aluminium – polypropylene flip-off cap.

SEFTRY 2,0 Powder for solution for injection:

White to yellowish powder in a 50 ml colourless vial, closed with grey rubber stoppers, the stoppers are fixed with aluminium rings. The vials are capped with a blue aluminium – polypropylene flip-off cap.

Holder of Certificate of Registration

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SEFTRY 1,0: 41/20.1.1/0870

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Access to the corresponding Professional Information

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