PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ADCO CEFAZOLIN 500 mg powder for solution for injection

ADCO CEFAZOLIN 1 g powder for solution for injection

ADCO CEFAZOLIN 500 mg

Each vial contains cefazolin sodium equivalent to 500 mg cefazolin

ADCO CEFAZOLIN 1 g

Each vial contains cefazolin sodium equivalent to 1 g cefazolin

Sugar free

Read all of this leaflet carefully before you are given ADCO CEFAZOLIN

- 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.

What is in this leaflet

1. What ADCO CEFAZOLIN is and what it is used for

2. What you need to know before you are given ADCO CEFAZOLIN

3. How to use ADCO CEFAZOLIN

4. Possible side effects

5. How to store ADCO CEFAZOLIN

6. Contents of the pack and other information

1. What ADCO CEFAZOLIN is and what it is used for

ADCO CEFAZOLIN is a cephalosporin antibiotic, used to treat many kinds of infections, including lung, skin, bone, joint, stomach, blood, heart valve and urinary tract infections, caused by bacteria sensitive to ADCO CEFAZOLIN.

2. What you need to know before you are given ADCO CEFAZOLIN

ADCO CEFAZOLIN should not be administered to you:

- If you are hypersensitive (allergic) to cefazolin, or any other cephalosporin or penicillin.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with ADCO CEFAZOLIN:

- Tell your doctor if you are penicillin sensitive
- Tell your doctor immediately if you develop an allergic reaction to ADCO CEFAZOLIN
- Tell your doctor if you have a history of gastrointestinal disease, particularly colitis. Mild diarrhoea is common with antibiotic use. However, a more serious form of diarrhoea (pseudomembranous colitis) may occur less frequently. This may develop while you use the antibiotic or within several months after you stop using it. Contact your doctor

right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur. Do not treat diarrhoea without first checking with your doctor

- Tell your doctor if you have or have ever had kidney disease. Your dosage may need to be adjusted
- If you have diabetes and regularly check your urine for sugar, use Clinistix or Tes-Tape. Do not use Clinitest tablets because cefazolin may cause false positive results.

Children

- The safety and effectiveness of the use of cefazolin in children younger than one month old, has not been confirmed.

Other medicines and ADCO CEFAZOLIN

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

Some medicines may interact with cefazolin. Before receiving ADCO CEFAZOLIN, tell your doctor if you are using any of the following medicines:

- Probenecid - the amount of ADCO CEFAZOLIN in your blood may be increased
- Oral contraceptives – your oral contraceptive may not work properly
- Aminoglycoside antibiotics – there is an increased risk of kidney damage.

Pregnancy, breastfeeding and fertility

The safety of ADCO CEFAZOLIN in pregnancy and breastfeeding has not been established. ADCO CEFAZOLIN easily passes through the placental barrier to reach the cord blood and amniotic fluid.

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 this medicine.

Driving and using machines

ADCO CEFAZOLIN is presumed to be safe or unlikely to produce an effect on the ability to drive and use machines.

ADCO CEFAZOLIN contains sodium

ADCO CEFAZOLIN 500 mg contains approximately 25,3 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1,27 % of the recommended maximum daily dietary intake of sodium for an adult.

ADCO CEFAZOLIN 1 g contains approximately 50,6 mg sodium, equivalent to 2,53 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive ADCO CEFAZOLIN

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

You will not be expected to give yourself [PRODUCT NAME]. It will be given to you by a person who is qualified to do so. ADCO CEFAZOLIN will be either injected into a large muscle (such as your buttock or hip) or added to an intravenous fluid that will drip through a needle or catheter placed in your vein.

Your doctor will prescribe an appropriate dose according to your condition.
Your doctor will tell you how long your treatment with ADCO CEFAZOLIN will last. Do not stop treatment early.
If you have the impression that the effect of ADCO CEFAZOLIN is too strong or too weak, tell your doctor or pharmacist.

If you receive more ADCO CEFAZOLIN than you should

Large doses of ADCO CEFAZOLIN may cause dizziness; numbness, tingling, pins and needles; and headache. Seizures may occur, particularly in patients with impaired kidney function.
Since a healthcare provider will administer ADCO CEFAZOLIN, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take ADCO CEFAZOLIN

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

4. Possible side effects

ADCO CEFAZOLIN can have side effects.

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

If any of the following happens, you must stop using ADCO CEFAZOLIN and 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
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO CEFAZOLIN. 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:

Frequent side effects:

- Severe diarrhoea
- Severe nausea or vomiting
- Severe stomach pain/cramps
- Unusual bleeding or bruising
- Bloody stools

- Vaginal irritation or discharge
- White spots in the mouth

Less frequent side effects:

- Fever, flu-like symptoms
- Hives, itching, swollen, or red skin
- Diarrhoea, stomach cramps, pain or tenderness
- Vomiting, loss of appetite
- Fatigue
- Sore throat
- A red or purple rash that spreads
- Widespread skin pain
- Genital itching
- Dry, cracked skin
- Vaginal pain and soreness
- Pain and swelling in one leg, chest pain, or numbness on one side of the body.

Frequency not known:

- Sudden swelling below the skin surface
- Bruising easily
- Bleeding from the nose, gums and GI (gastrointestinal) tract
- Headache and dizziness
- Blood in the urine

- Increased or decreased urine output
- Jaundice, which is a yellowing of your skin and the white of your eyes;
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

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 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 ADCO CEFAZOLIN.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store ADCO CEFAZOLIN

Store all medicines out of reach of children.

Store the dried powder at or below 25 °C (room temperature). Do not remove vials from outer carton until required for use.

Once reconstituted, the solution is to be used within 36 hours if stored below 25 °C (room temperature) and within 96 hours if stored at 2 – 8 °C (in the refrigerator).

Do not use ADCO CEFAZOLIN if you notice that the reconstituted solution appears cloudy.

6. Contents of the pack and other information

What ADCO CEFAZOLIN contains:

ADCO CEFAZOLIN 500 mg: Each vial contains cefazolin sodium equivalent to 500 mg cefazolin.

ADCO CEFAZOLIN 1 g: Each vial contains cefazolin sodium equivalent to 1 g cefazolin.

What ADCO CEFAZOLIN looks like and contents of the pack

ADCO CEFAZOLIN 500 mg powder for solution for injection is a 10 ml colourless glass vial sealed with a grey rubber stopper and an aluminium cap. It contains white or almost white sterile cefazolin powder for injection. The reconstituted solution is clear and colourless.

ADCO CEFAZOLIN 1 g powder for solution for injection is a 10 ml colourless glass vial sealed with a grey rubber stopper and an aluminium cap. It contains white or almost white sterile cefazolin powder for injection. The reconstituted solution is clear and colourless.

ADCO CEFAZOLIN 500 mg and 1 g powder for solution for injection vials are supplied in cartons containing 10 units (vials).

Holder of Certificate of Registration

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