PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ADCO CEFTRIAXONE 500 mg powder for injection

ADCO CEFTRIAXONE 1 g powder for injection

ADCO CEFTRIAXONE 2 g parenteral infusion

ADCO CEFTRIAXONE 500 mg: Each vial contains 500 mg sterile ceftriaxone as ceftriaxone sodium.

ADCO CEFTRIAXONE 1 g: Each vial contains 1 g sterile ceftriaxone as ceftriaxone sodium.

ADCO CEFTRIAXONE 2 g: Each vial contains 2 g sterile ceftriaxone as ceftriaxone sodium.

Sugar Free

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

- 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 ADCO CEFTRIAXONE is and what it is used for
2. What you need to know before you use ADCO CEFTRIAXONE
3. How to use ADCO CEFTRIAXONE
4. Possible side effects
5. How to store ADCO CEFTRIAXONE
6. Contents of the pack and other information

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

ADCO CEFTRIAXONE is an antibiotic given to adults and children (including new-born babies), that belongs to a group of medicines called cephalosporins. It works by killing bacteria that cause infections.

ADCO CEFTRIAXONE is used to treat infections of:

- the brain (meningitis)
- the middle ear
- the abdomen and abdominal wall (peritonitis)
- the urinary tract and kidneys
- bones and joints
- the skin or soft tissues
- the blood
- the lungs
- the ear, nose and throat
- the intestines.

It can be given:

- to treat specific sexually transmitted infections (gonorrhoea and syphilis)
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection
- to treat infections of the chest in adults with chronic bronchitis
- to treat Lyme disease (caused by tick bites) in adults and children including new-born babies from 15 days of age
- to prevent infections during surgery.

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

ADCO CEFTRIAXONE should not be administered to you:

- If you are hypersensitive (allergic) to ceftriaxone or any of the other ingredients of ADCO CEFTRIAXONE (listed in section 6)
- If you are hypersensitive (allergic) to cephalosporins or penicillins (see section 2 warnings and precautions)

Lidocaine (lignocaine) solution should never be administered to you intravenously.

ADCO CEFTRIAXONE must not be given to babies if:

- The baby is premature
- The baby is new-born (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 healthcare provider before being given the injection:

- If you have recently received or are about to receive products that contain calcium
- If you have a coagulation (blood clot) disorder
- If you have recently had diarrhoea after having an antibiotic medicine
- If you have ever had problems with your gut, in particular colitis (inflammation of the bowel)
- If you have gall stones or kidney stones
- If you have other illnesses, such as blood problems in children (such as jaundice)
- If you have allergies, particularly to cephalosporins, penicillins, or similar antibiotics as you may be at greater risk of hypersensitivity to ceftriaxone

- If 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)
- If you have anaemia (low levels of red blood cells)
- If you have any kidney or liver problems.

Children and adolescents

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

Other medicines and ADCO CEFTRIAXONE

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines.

- ADCO CEFTRIAXONE should not be added to solutions containing calcium
- Unwanted effects have been observed with the combination of medicines containing chloramphenicol (antibiotic mainly used for treating eye and ear infections) and ceftriaxone
- If you are taking medicine to reduce the clotting of your blood, tell your doctor before you receive ADCO CEFTRIAXONE.

If you need a blood or urine test

If you are given ADCO CEFTRIAXONE for a long time, you may need to have regular blood tests. ADCO CEFTRIAXONE 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 ADCO CEFTRIAXONE
- 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 ADCO 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, 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 this medicine.

Ceftriaxone crosses the placental barrier and is passed into breast-milk.

Safety in pregnancy and lactation has not been established. You should not receive ADCO CEFTRIAXONE when you are pregnant or breastfeeding your baby.

Driving and using machines

ADCO CEFTRIAXONE may affect your mental and/or your physical abilities to perform or execute tasks or activities requiring your mental alertness, judgment and/or sound coordination and vision.

ADCO CEFTRIAXONE 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.

3. How to use ADCO CEFTRIAXONE

ADCO CEFTRIAXONE may be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.

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

Your doctor will tell you how long your treatment with ADCO CEFTRIAXONE will last. If you have the impression that the effect of ADCO CEFTRIAXONE is too strong or too weak, tell your doctor or pharmacist.

The usual dose

Your doctor will decide the correct dose of ADCO CEFTRIAXONE for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age and how well your kidneys and liver are working.

If you take more ADCO CEFTRIAXONE than you should

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

If you forget to use ADCO CEFTRIAXONE

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

Effects when treatment with ADCO CEFTRIAXONE is stopped:

The duration of ADCO CEFTRIAXONE therapy varies, depending on the nature of your illness and your individual response to the treatment.

You will receive ADCO CEFTRIAXONE 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

ADCO CEFTRIAXONE can have side effects.

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

If any of the following happens, stop using ADCO CEFTRIAXONE 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
- Anaphylactic shock and anaphylactoid reactions (serious life-threatening allergic reaction which usually occurs within few seconds or minutes of exposure to allergic substances. This involves hives, swelling and sudden drop in the blood pressure and sometimes shock)
- Severe skin reactions: Exanthema (a skin rash accompanying a disease or fever), allergic dermatitis (skin irritation), pruritis (itching), urticaria (hives), oedema (swelling caused due to excess fluid accumulation in the body tissues). Stevens-Johnson syndrome or Lyell's syndrome/ toxic epidermal necrolysis (severe skin reaction with blisters or peeling of the skin and possibly blisters in the mouth). 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).

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

- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting ADCO CEFTRIAXONE treatment for infections with spirochaete such as Lyme disease
- A brain disorder (encephalopathy), particularly in elderly patients. Some signs may be an altered mental state, muscle jerks and fits
- Watery diarrhoea that lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of serious bowel inflammation (colitis, pseudomembranous colitis) that can happen after taking antibiotics
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back, nausea and vomiting.

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/ diarrhoea
- Changes in the results of blood tests for liver functions
- Rash.

Less frequent side effects

- Fungal infections (for example, thrush)
- Thrombocytopenia, leukopenia, lymphopenia, eosinophilia, granulocytopenia, agranulocytosis (disorders of the blood)

- Haemolytic anaemia (a disorder in which red blood cells are destroyed faster than they can be made)
- 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
- Pruritis (itching)
- Phlebitic reactions (inflammation of veins causing pain, discomfort and swelling)
- Pain where the injection was given
- Abnormal kidney function test (blood creatinine increased)
- Fever
- Shivering
- Wheezing
- Temporary liver problems
- Other types of infection, e.g. yeasts
- 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)
- Nausea
- Vomiting
- Stomatitis (inflammation of the mouth and lips)

- Precipitation of ceftriaxone salts in the gallbladder
- Haematoma or bleeding
- Oliguria (low urine output)
- Genital mycosis (fungal infection)
- Hepatotoxicity (liver damage)
- A secondary infection that may not respond to the antibiotic previously prescribed
- Sweating
- Flushing
- Convulsions
- Vertigo (spinning sensation)
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue
- A neurological condition that may occur in neonates with severe jaundice (kernicterus).

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

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 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 CEFTRIAXONE.

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

5. How to store ADCO CEFTRIAXONE

Store in a dry cool place, at or below 25 ºC, protected from light.

Storage directions for reconstituted product: Store for up to 6 hours at 25 °C or 24 hours at 2 – 8 °C.

Single dose unit. Discard any unused portion of solution.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What ADCO CEFTRIAXONE contains

The active substance is ceftriaxone.

ADCO CEFTRIAXONE 500 mg: Each vial contains 500 mg sterile ceftriaxone as ceftriaxone sodium.

ADCO CEFTRIAXONE 1 g: Each vial contains 1 g sterile ceftriaxone as ceftriaxone sodium.

ADCO CEFTRIAXONE 2 g: Each vial contains 2 g sterile ceftriaxone as ceftriaxone sodium.

There are no other ingredients.

What ADCO CEFTRIAXONE looks like and contents of the pack

10 ml clear, colourless glass vial containing an almost white or yellowish sterile crystalline powder with an aluminium cap.

ADCO CEFTRIAXONE 1 g:

10 ml clear, colourless glass vial containing an almost white or yellowish sterile crystalline powder with an aluminium cap.

ADCO CEFTRIAXONE 2 g:

50 ml clear, colourless glass vial containing an almost white or yellowish sterile crystalline powder with an aluminium cap.

Reconstituted solutions may vary in colour from pale yellow to amber, depending on the concentration and length of storage.

Packs for* IM *or* IV*. injection containing:

Single vials of dry substance equivalent to 500 mg ceftriaxone packed in 1s, 4s, 5s or 10s in an outer carton.

***Packs for* IM *or* IV *injection containing*:**

Single vials of dry substance equivalent to 1 g ceftriaxone packed in 1s, 4s, 5s or 10s in an outer carton.

***Packs for* IV *infusion containing*:**

1 vial with dry substance equivalent to 2 g ceftriaxone packed in 1s, 4s, 5s or 10s in an outer carton.

Holder of Certificate of Registration

ADCOCK INGRAM CRITICAL CARE (PTY) LTD

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Aeroton

Johannesburg, 2013

Tel: 011 494 8000

This leaflet was last revised in

14 April 2025

REGISTRATION NUMBER:

ADCO CEFTRIAXONE500 mg: 37/20.1.1/0042

ADCO CEFTRIAXONE1 g: 37/20.1.1/0043

ADCO CEFTRIAXONE2 g: 37/20.1.1/0044

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ADCO CEFTRIAXONE 500 mg:	NS2 04/20.1.1/1959
ADCO CEFTRIAXONE 1 g:	NS2 04/20.1.1/1957
ADCO CEFTRIAXONE 2 g:	NS2 04/20.1.1/1958

Botswana:	
ADCO CEFTRIAXONE 500 mg:	S2 BOT0801463
ADCO CEFTRIAXONE 2 g:	S2 BOT1001650