

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

IMIPENEM AND CILASTATIN ADCO 500 mg/20 ml

Powder for Solution for Infusion

Imipenem and Cilastatin

Sugar free

Read all of this leaflet carefully before you are given IMIPENEM AND

CILASTATIN ADCO

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

1. What IMIPENEM AND CILASTATIN ADCO is and what it is used for

IMIPENEM AND CILASTATIN ADCO belongs to a group of highly effective antibiotic medicines called carbapenems. It is used for the treatment of a wide range of bacterial infections that can occur in various parts of the body such as:

- Infections within the abdomen
- Infections affecting the lungs
- Gynaecological infections
- Infections of the blood
- Complicated and uncomplicated urinary tract infections
- Bone and joint infections
- Skin and soft tissue infections
- Infection of the heart's inner lining, usually involving the heart valves
- To reduce the risk of infection in adult patients after colorectal surgery.

IMIPENEM AND CILASTATIN ADCO should not be used for the treatment of meningitis.

2. What you need to know before you are given IMIPENEM AND CILASTATIN ADCO

IMIPENEM AND CILASTATIN ADCO should not be administered to you:

- if you are hypersensitive (allergic) to imipenem and cilastatin or any of the other ingredients of IMIPENEM AND CILASTATIN ADCO (listed in section 6)

- if you are hypersensitive (allergic) to any other carbapenem antibacterial medicine
- if you have meningitis
- if you are pregnant or breastfeeding.

Warnings and precautions

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

- if you have meningitis
- if you previously had an allergic reaction during treatment with another beta-lactam antibiotic (penicillins or cephalosporins)
- if you have liver, kidney or urinary problems
- if you have a history of gastrointestinal disease, particularly colitis
- if you have any central nervous system disorders such as localised tremors or epileptic seizures
- if you are receiving valproic acid or divalproex sodium.

Children

IMIPENEM AND CILASTATIN ADCO may be used in children with sepsis (a life-threatening complication of an infection) as long as they are not suspected of having meningitis.

Other medicines and IMIPENEM AND CILASTATIN ADCO

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

(This includes all complementary or traditional medicines.)

Caution should be exercised when combining IMIPENEM AND CILASTATIN ADCO with other beta-lactam antibiotics.

IMIPENEM AND CILASTATIN ADCO should not be used together with ganciclovir as this could cause localised seizures.

Receiving carbapenems, including imipenem, along with valproic acid or divalproex sodium reduces the concentrations of valproic acid. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures.

Simultaneous administration of antibiotics with warfarin may increase its blood thinning effects.

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.

Safety in pregnancy and lactation has not been established. IMIPENEM AND CILASTATIN ADCO should therefore not be used during pregnancy.

Small amounts of this medicine may pass into breast milk and it may affect the baby. If the use of IMIPENEM AND CILASTATIN ADCO is deemed necessary, then you should stop breastfeeding.

No data is available regarding potential effects of IMIPENEM AND CILASTATIN ADCO treatment on male or female fertility.

Driving and using machines

There are some side effects (such as hallucination, dizziness, sleepiness and loss of balance) associated with IMIPENEM AND CILASTATIN ADCO that may affect your ability to drive or operate machinery.

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

IMIPENEM AND CILASTATIN ADCO contains sodium bicarbonate (sterile)

This medicine contains 37,6 mg sodium per vial. This is to be taken into consideration by patients on a controlled sodium diet.

3. How IMIPENEM AND CILASTATIN ADCO is given

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

IMIPENEM AND CILASTATIN ADCO is administered into your vein over a period of time (intravenous infusion).

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

Your doctor will decide on the dosage depending on the severity of the infection, your kidney function and body mass.

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

If you take more IMIPENEM AND CILASTATIN ADCO than you should

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

If you forget to take IMIPENEM AND CILASTATIN ADCO

Since a healthcare professional will administer IMIPENEM AND CILASTATIN ADCO, it is unlikely that the dose will be missed.

4. Possible side effects

IMIPENEM AND CILASTATIN ADCO can have side effects.

Not all side effects reported for IMIPENEM AND CILASTATIN ADCO are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking IMIPENEM AND CILASTATIN ADCO, please consult your healthcare provider for advice.

If any of the following happens, stop taking / using IMIPENEM AND CILASTATIN ADCO 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
- Kounis syndrome - chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction
- rash or itching
- fainting
- severe allergic reaction of the skin such as wheals, hives or welts, itching, redness of skin, skin rash
- Stevens-Johnson syndrome (skin disease)
- toxic exfoliation of skin

- inflammation and scaling of the skin.

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

- chest pain
- angina
- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of recurrent infections such as fever or sore throat
- less urine than is normal for you
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- inflammation of the colon which results in abdominal cramps or pain, tenderness, severe, watery diarrhoea which may also be bloody, fever, gastro-enteritis
- decreased number of blood platelets in your blood with symptoms such as easy and excessive bleeding, bruising easily and nose bleeds
- psychic disturbances including hallucinations
- confusional states
- rapid contraction and extension of a muscle

- seizures
- sleepiness or unusual drowsiness
- burning, crawling, itching, numbness, prickling, “pins and needles”, or tingling feelings
- linear IgA disease - rash with blisters arranged in a circle with central crusting or like a string of pearls.
- shaking/trembling of specific body parts
- aggravation of myasthenia gravis (a neuromuscular disease characterised by muscle weakness)
- bluish discolouration of the skin due to poor circulation or inadequate oxygenation of the blood
- shortness of breath
- hyperventilation
- haemorrhagic colitis (bacterial infection of the large intestine that causes diarrhoea, abdominal pain, bloody stools, nausea, and vomiting)
- failure of the kidneys to produce urine
- an increase in the need to pass water
- acute kidney failure
- agitation
- uncontrolled, involuntary muscle movement.

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:

- eosinophilia (blood disorder - high levels of eosinophils in blood)
- thrombophlebitis (inflammation of a vein)
- nausea
- vomiting
- diarrhoea
- rash
- increases in serum transaminase (from blood tests)
- increases in serum alkaline phosphatase (from blood tests).

Less frequent side effects:

- fungal infection typically on the skin or mucous membranes (thrush)
- decrease in white blood cell count
- decrease in number of granulocytes, may include symptoms like lesions of the throat and other mucous membranes, gastrointestinal tract, and of the skin, haemolytic anaemia
- bone marrow depression
- dizziness
- altered sense of taste
- headache
- hearing loss

- vertigo
- noise or ringing in the ears
- low blood pressure
- flushing
- throat pain
- staining of teeth and/or tongue
- abdominal pain
- heartburn
- inflammation of the tongue
- swollen tongue
- increased salivation
- liver dysfunction
- inflammation of the liver, fulminant hepatitis
- redness of the skin
- itching skin
- bullseye pattern rash
- Stevens-Johnson syndrome (skin disease)
- toxic exfoliation of skin
- inflammation and scaling of the skin
- pain in several joints of the body
- thoracic spine pain
- reddish urine discolouration (harmless and should not be confused with haematuria)
- itching of the vulva
- local pain and induration at the injection site, redness of skin at the injection site, fever, chest discomfort, loss of strength or energy/weakness

- a positive direct Coombs' test, prolonged prothrombin time, decreased haemoglobin, increases in serum bilirubin, elevations in serum creatinine, elevations in blood urea nitrogen (from blood tests)

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 IMIPENEM AND CILASTATIN ADCO.

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 IMIPENEM AND CILASTATIN ADCO

Store all medicines out of reach of children.

Store at or below 25 °C and protect from light.

Reconstituted solution

Do not freeze the reconstituted solution. Diluted solutions should be used immediately.

Storage conditions after reconstitution:

If stored at room temperature ($25 \pm 2^\circ\text{C}$), The reconstituted solution should be administered within 4 hours after reconstitution.

If stored in the Refrigerator ($5 \pm 3^\circ\text{C}$), The reconstituted solution should be administered within 24 hours after reconstitution.

6. Contents of the pack and other information

What IMIPENEM AND CILASTATIN ADCO contains

The active substance is imipenem monohydrate equivalent to 500 mg of anhydrous imipenem and cilastatin sodium equivalent to 500 mg cilastatin.

The other ingredients are 20 mg sodium bicarbonate (sterile).

What IMIPENEM AND CILASTATIN ADCO looks like and contents of the pack

IMIPENEM AND CILASTATIN ADCO is a white to almost white or light (pale) yellow powder for solution for infusion.

IMIPENEM AND CILASTATIN ADCO is packaged in 20 ml colourless type III glass vials, sealed with a type I bromobutyl rubber stopper and an aluminium flip-off cap.

IMIPENEM AND CILASTATIN ADCO 500 mg/20 ml
Powder for Solution for Infusion
Email: Aicc.RegulatoryAffairs@adcock.com

Adcock Ingram Critical Care (Pty) Ltd.
02 April 2025

Holder of Certificate of Registration

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