Patient Information Leaflet

SCHEDULING STATUS

S4

BACQURE 500 Powder for injection

Imipenen and Cilastatin

Sugar free

Contains sodium: 36,14 mg per bottle

Read all of this leaflet carefully before you receive BACQURE 500

- 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 the leaflet

1. What BACQURE 500 is and what it is used for
2. What you need to know before you take BACQURE 500
3. How to take BACQURE 500
4. Possible side effects
5. How to store BACQURE 500
6. Contents of the pack and other information

1. What BACQURE 500 is and what it is used for

BACQURE 500 belongs to a group of medicines called thienamycins. It kills a wide range of bacteria (germs) that cause infections in various parts of the body.

BACQURE 500 is used for the treatment of several bacterial infections, except meningitis.

2. What you need to know before you receive BACQURE 500

You should not receive BACQURE 500 if:

- if you have had an allergic reaction to imipenem and cilastatin or similar antibiotics (including penicillin or cephalosporin) or to any of the ingredients (listed in section 6). (An allergic reaction may include rash, itching, swelling of face/lips/tongue/hands/feet or breathing difficulties.)
- if you are pregnant or planning to become pregnant or breastfeeding.
- if you are suffering from meningitis (which is inflammation of the membranes surrounding the brain and spinal cord).

Please inform your doctor, even if these statements were applicable to you at any time in the past.

Warnings and precautions

Tell your doctor or healthcare provider before being given BACQURE 500:

- if you had history of convulsions (fits) in past.
- if you are have had kidney problems.
- if you have severe diarrhoea (which may contain blood or mucous) along with stomach cramps (symptoms of a condition known as pseudomembranous colitis).
- if you have liver problems.
- if you have a serious allergic reaction that could lead to heart problems.

You may develop a positive test (Coombs test) which indicates the presence of antibodies that may destroy red blood cells. Your doctor will discuss this with you.

Other medicines and BACQURE 500

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

- Medicines used to treat infections e.g. amoxicillin, ganciclovir.
- Valproic acid used to treat seizures.
- Medicines used to prevent blood clots from forming e.g. aspirin, warfarin.
- Probenecid used to treat gout.

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 receiving BACQURE 500.

Driving and using machines

There are some side effects associated with BACQURE 500 (such as seeing, hearing, or feeling something that is not there, dizziness, sleepiness, and a spinning sensation) that may affect your ability to drive or operate machinery (see section 4).

BACQURE 500 contains sodium

BACQURE 500 contains 36,14 mg sodium (main component of cooking/table salt) in each bottle. This is equivalent to 1,807 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW BACQURE 500 IS GIVEN

An injection will be administered into a vein (intravenous injection) by a healthcare provider. The number of injections you require will depend upon your condition.

If you receive more BACQURE 500 than you should

Since a healthcare provider will administer BACQURE 500, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you do not receive BACQURE 500

Since a healthcare provider will administer BACQURE 500, it is unlikely that the dose will be missed.

4. Possible side effects

BACQURE 500 may cause side effects. Not all side effects reported for BACQURE 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BACQURE 500, please consult your healthcare provider for advice.

If any of the following happens your healthcare provider will stop BACQURE 500 immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- blistering and/or peeling of the skin,
- fainting.

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to BACQURE 500 and you may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- severe diarrhoea (which may contain blood or mucous) along with stomach cramps,
- bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia, fever,
- myoclonic activity (shock-like contractions of a portion of a muscle, an entire muscle or a group of muscles restricted to one area of the body or in several areas),
- hallucinations and confusion, memory loss,
- convulsions (fits),
- worsening of a rare disease associated with muscle weakness,
- loss of hearing,
- bluish discoloration of the face and lips,
- irregular heartbeat, the heart beating forcefully or rapidly,
- swelling and redness along a vein which is extremely tender when touched,
- difficulty breathing, abnormally fast and superficial breathing,
- yellowing of skin and whites of eyes, dark urine, and tiredness which may be symptoms of liver problems,
- swelling of face, ankles or other parts of the body, with sudden increase or decrease in the amount of urine passed, or blood in the urine, changes in urine colour.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea or vomiting,

Less frequent side effects:

- fungal infection,
- dizziness, increased sleepiness,
- pins and needle sensations of toes and fingers, tremors, taste disturbance, headache,
- ringing in the ears,
- low blood pressure, reddening of the skin,
- sore throat,
- staining of teeth and tongue, stomach pain, heartburn, red swollen tongue, overgrowth of the normal projections on the tongue giving it a hairy appearance, increase in the production of saliva,
- excessive sweating, changes in the texture of the skin,
- pain in the joints, pain in the upper spine,
- itching of the skin just outside the vagina in women,
- fever,
- redness, itching, swelling and pain at the site of injection, chest discomfort, weakness,

Side effects with unknown frequency:

- agitation,
- uncontrolled, involuntary muscle movement.
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

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. 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 BACQURE 500.

Reporting suspected adverse reactions after authorisation of PATRAM is important. It allows continued monitoring of the benefit/risk balance of PATRAM. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

Suspected adverse reactions can also be reported directly to the Holder of Certificate of Registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

5. How to store BACQURE 500

- Store all medicines out of reach of children.
- Store the dry powder below 25 °C and protect from light. Protect from freezing.
- The container must be stored in the carton until required for use. After reconstitution, the solution may be kept for 4 hours at 25 °C or for 24 hours under refrigeration (4 °C). The product is for single use only and any unused portion must be discarded.
- Do not use after the expiry date stated on the label.
- 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 BACQURE 500 contains

The active substances are imipenem (sterile) equivalent to anhydrous imipenem 500 mg and cilastatin sodium (sterile) equivalent to cilastatin 500 mg.

The other ingredient is sodium bicarbonate.

What BACQURE 500 looks like and contents of the pack

White to pale yellow powder filled in 100 ml moulded clear glass infusion bottle sealed with rubber plug and flip off seal. After reconstitution a clear, pale yellow to yellow coloured solution is formed.

Each carton contains one 100 ml clear, colourless glass infusion bottle sealed with a light grey rubber plug and sealed with a tear off seal having a red coloured polypropylene flip off disc.

White to pale yellow powder filled in clear glass vial sealed with grey rubber plug and flip off seal. After reconstitution a clear, pale yellow to yellow coloured solution is formed.
Each carton contains one 30 ml clear glass USP Type 1 vial with grey bromobutyl rubber plug and polypropylene flip off seal.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To follow