1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SAB-CEFOTAXIME 500 injection

SAB-CEFOTAXIME 1 g injection

cefotaxime sodium

Sugar free

Contains sodium:

SAB-CEFOTAXIME 500: Each gram of cefotaxime contains 24 mg of sodium.

SAB-CEFOTAXIME 1 g: Each gram of cefotaxime contains 48 mg of sodium.

Read all of this leaflet carefully before you start taking SAB-CEFOTAXIME.

- 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.
- **SAB-CEFOTAXIME** 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.
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What is in this leaflet:

1. What SAB-CEFOTAXIME is and what it is used for

SAB-CEFOTAXIME contains cefotaxime. Cefotaxime belongs to a group of medicines known as cephalosporin antibiotics. Cefotaxime is an antibiotic used to treat infections in different parts of the body caused by bacteria.

SAB-CEFOTAXIME is used for the treatment of the following common infections:

- Genito-urinary tract [infection of bladder, kidney and reproductive tract (gonorrhoea)]
- Skin and soft tissue (infections of the skin like sellulitis, impetigo, furunculosis, abscess)
- Respiratory tract (infection of lungs and airways such as sinusitis, pneumonia, pharyngitis, follicular tonsillitis, scarlet fever, bronchitis, septic sore throat)
- Ear (otitis media)
- Gastro-intestinal tract (infections of stomach and bowel such as enteritis, dysentery)
- Meningitis in children (infections around the brain or spinal cord)
- Sepsis (whole-body inflammation caused by severe infection)

Cefotaxime works by killing bacteria that are causing your infection.

2. What you need to know before are given SAB-CEFOTAXIME

SAB-CEFOTAXIME should not be administered to you if:

- If you are hypersensitive (allergic) to cefotaxime or to any cephalosporin antiobiotics or to any of the other ingredients of **SAB-CEFOTAXIME** (listed in section 6). The symptoms of an allergic reaction include rash, itching, swelling of face, lip/hands/feet or breathing diffculties.
- If you have had a severe allergic reaction to penicillin and other beta-lactam antiobiotics.

Do not take **SAB-CEFOTAXIME** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Tell your doctor or health care provider before being given the injection**:**

- if you are allergic or sensitive to pencillin
- if you have a history of allergy
- if you have kidney problems
- if you are going to taake certain blood/urine tests
- if you develop any other infection while on treaatment with cefotaxime
- if you develop severe diarrhoea while on treatment with cefotaxime. Treatment should be discontinued if sevre diarrhoea develops.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking **SAB-CEFOTAXIME**.

Other medicines with SAB-CEFOTAXIME

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

Take care if you are using any of the following medicines with **SAB-CEFOTAXIME**

- Aminoglycosides such as gentamicin (medicine used to treat bacterial infections)
- Furosemide (water tablet)
- Probenecid (medicine used to treat painful, swollen joints caused by uric acid crystals)
- Other antibiotics (medicines that prevent the growth of the bacteria).

You should always tell your doctor about other medicines that you are taking with or without prescription.

If you have test your urine for sugar while you are being given **SAB-CEFOTAXIME** make sure your doctor knows which type of test you use. This medicine may affect the results of some of these tests.

If you have to have any blood tests, tell your doctor you are being given **SAB-CEFOTAXIME**. This medicine may affect the results of some blood tests.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before being administered **SAB-CEFOTAXIME**.

Driving and using machines

Make sure you know how you react to **SAB-CEFOTAXIME** before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

SAB-CEFOTAXIME contains sodium:

SAB-CEFOTAXIME 500 and 1000 contains 24 mg and 48 mg sodium respectively in each dosage unit. This is equivalent to 1,2 % and 2,4 % respectively of the recommended maximum daily dietary intake of sodium of an adult.

3. How SAB-CEFOTAXIME will be administered

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

For prevention of infections

The minimum effective dose will be 1 g **SAB-CEFOTAXIME** 30 – 90 minutes prior to surgery.

For the treatment of infections

Adults

The usual dose will depend on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will decide on the dose that you need.
The usual dose is 2 g dose per day in divided doses.

Your doctor may increase the dose to 3 to 4 g per day in divided doses depending on the severity of your illness.

Paediatrics

Use in infants and children:

The usual dose for children of 50- 100 mg/kg body mass per day in divided doses.

Your doctor may increase the dose up to 200 mg/kg body mass per day in divided doses depending on severity of your illness.

Neonates:

The recommended dosage regimen for neonates is as follows:

0 -7 days (1 week) of age: 50 mg/kg IV at 12 hour intervals.

7-28 days (1-4 weeks) of age: 50 mg/kg IV at 8 hour intervals

The dosages above are applicable to both premature and full term infants.

Patients with kidney problems

Your doctor will decide the appropriate dose for you.

Your doctor will tell you how long your treatment with **SAB-CEFOTAXIME** will last. Do not stop treatment early. If you have the impression that the effect of **SAB-CEFOTAXIME** is too strong or too weak, tell your doctor or pharmacist.

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

If you have been given more SAB-CEFOTAXIME than you should

Since a health care provider will administer **SAB-CEFOTAXIME**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose

Since a health care provider will administer **SAB-CEFOTAXIME**, it is unlikely that the dose will be missed.

If you stop takingSAB0CEFOTAXIME

Since a health care provider will administer **SAB-CEFOTAXIME**, your doctor will tell you how long your treatment with **SAB-CEFOTAXIME** will last.

4. Possible side effects

SAB-CEFOTAXIME can have side effects.

Not all side effects reported for **SAB-CEFOTAXIME** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SAB-CEFOTAXIME**, please consult your health care provider for advice.

If any of the following happens, you should not be given **SAB-CEFOTAXIME** and you should tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, shortness of breath;
- rash or itching;
- Extremely serious allergic skin reaction (Steven-Johnsons Syndrome).

- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).
- drug-induced enterocolitis syndrome (DIES):

  DIES has been reported mainly in children receiving cefotaxime. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **SAB-CEFOTAXIME**. 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 infections such as fever, severe chills, sore throat or mouth ulcers (neutropenia)
- Bleeding or bruising more easily than normal (thrombocytopenia)
- Bleeding complications related to blood disorder leading to an increased physiological risk for bleeding (hypoprothrombinaemia) and/or dysfunction of blood cells which help blood to clot may occur.
- Fever, rash, enlarged kidneys, low back pain, painful urination, abnormal urination frequency (acute interstitial nephritis, renal tubular necrosis, nephrotoxicity)
- Nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine, inflammation of liver (hepatitis, cholestatic jaundice)
- Fits (convulsions)

- Severe diarrhoea, usually with blood and mucus, stomach pain, fever (pseudomembranous colitis)
- Pain at the site of injection, skin redness or inflammation, swelling (oedema) of the extremities (ankle and foot), palpable cord-like veins (thrombophlebitis).

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:

- Tenderness and pain with redness and/or swelling at the site of injection

Less frequent side effects:

- Diarrhoea
- Headache
- Decreased number of red blood cells
- Tendency to bleed/bruise easily
- Thrush
- Infection in gut (colitis)
- Lack of awareness, loss of consciousness
- Inability to control movements.

Side effects occurring with an unknown frequency:

- Nausea and vomiting
- Dehydration
- Fever
- Loss of appetite

- Sores in the mouth and throat
- Increased heart rate
- Trouble breathing
- Joint pain
- Yellowing of skin and eyes
- Fatigue
- Burning sensation with urination
- Dizziness;
- Confusion and anxiety
- Sweating
- Bloody, watery diarrhoea
- Stomach cramps or pain
- Vaginal itching or soreness
- Sensitivity to light and blurred vision

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:

- The Pharmacovigilance Unit at Innovata: +27 869 990 912 (tel), or
- SAHPRA via the "6.04 Adverse Medicine Reactions 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 **SAB-CEFOTAXIME**.

5. How to store SAB-CEFOTAXIME

- Store all medicines out of reach of children.
- Before reconstitution dry powder should be stored at or below 25 °C, protected from light.
- The vial must be stored in the carton until required for use.
- Reconstituted solution to be stored in original vial.
- After reconstitution do not freeze.
- Any unused portion must be discarded.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What **SAB-CEFOTAXIME** contains:

The active substance is cefotaxime sodium equivalent to cefotaxime.

SAB-CEFOTAXIME 500:

The active substance is cefotaxime sodium equivalent to cefotaxime 500 mg. Each vial of **SAB-CEFOTAXIME** contains 500 mg of cefotaxime.

SAB-CEFOTAXIME 1 g:

The active substance is cefotaxime sodium equivalent to cefotaxime 1 g. Each vial of **SAB-CEFOTAXIME** contains 1 g of cefotaxime.

SAB-CEFOTAXIME 500 mg also contains 24 mg of sodium as a buffer.

SAB-CEFOTAXIME 1 g also contains 48 mg of sodium as a buffer.

What SAB-CEFOTAXIME looks like and contents of the pack

SAB-CEFOTAXIME 500:

Carton containing vial of 500 mg in clear, colourless glass USP Type 1 vial.

White or slightly yellow powder, hygroscopic, filled in 15 ml USP type I clear, colourless glass vial with grey rubber plug and coloured flip-off seal.

SAB-CEFOTAXIME 1 g:

Carton containing vial of 1 g in clear, colourless glass USP Type 1 vial.

White or slightly yellow powder, hygroscopic, filled in 15 ml USP type I clear, colourless glass vial with grey rubber plug and coloured flip-off seal.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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