

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD

Product proprietary name: RAZOBIN 2 mg/3 mg/4 mg

Dosage form and strength: Lyophilized Powder for Injection 2.25 g/3.375 g/4.5 g

Date:

29/01/2024

Patient Information Leaflet

S4

RAZOBIN 2 (Lyophilised powder for solution for injection/infusion)

RAZOBIN 3 (Lyophilised powder for solution for injection/infusion)

RAZOBIN 4 (Lyophilised powder for solution for injection/infusion)

Piperacillin sodium / Tazobactam sodium

Read all of this leaflet carefully before RAZOBIN is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **RAZOBIN** 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.

1. WHAT RAZOBIN CONTAINS

The active substances are piperacillin sodium and tazobactam sodium.

RAZOBIN 2:

Each vial contains piperacillin sodium and tazobactam sodium cryodesiccated powder for solution for injection/infusion equivalent to piperacillin 2, 0 g and tazobactam 0, 25 g.

Each vial contains 4, 7 milli-equivalents (108 mg) of sodium.

RAZOBIN 3:

Each vial contains piperacillin sodium and tazobactam sodium cryodesiccated powder for solution for injection/infusion equivalent to piperacillin 3, 0 g and tazobactam 0, 375 g.

Each vial contains 7, 05 milli-equivalents (162 mg) of sodium.

RAZOBIN 4:

Each vial contains piperacillin sodium and tazobactam sodium cryodesiccated powder for solution for injection/infusion equivalent to piperacillin 4, 0 g and tazobactam 0, 5 g.

Each vial contains 9, 40 milli-equivalents (216 mg) of sodium.

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2. WHAT RAZOBIN IS USED FOR

RAZOBIN injection contains two active ingredients, piperacillin, which is a penicillin-type antibiotic, and tazobactam, which is a medicine that prevents bacteria from inactivating piperacillin.

RAZOBIN is used to treat bacterial infections such as those affecting your chest, abdomen, skin and gynaecological infections.

RAZOBIN may also be used with medicines known as “aminoglycosides” to treat infections in patients who are unable to fight infections normally.

RAZOBIN is used to treat bacterial infections in children under 12 years of age with low white blood cell counts (neutropenia) and hence decreased ability to fight infection (used in combination with an aminoglycoside antibiotic for this purpose).

In hospitalised children aged 2 to 12 years, **RAZOBIN** is used to treat serious infections in the abdomen.

RAZOBIN is not recommended to treat abdominal infections in children under 2 years.

3. BEFORE YOU RECEIVE RAZOBIN

You should not receive RAZOBIN:

- If you have ever had an unusual or allergic reaction to **RAZOBIN**, antibiotics known as penicillins or cephalosporins, or to medicines called beta-lactamase inhibitors.
- If you are pregnant or breastfeeding.

Take special care with RAZOBIN

Before receiving RAZOBIN:

- Tell your doctor if you are allergic to penicillins, cephalosporins, any other medications, or have a history of allergy. Stop taking **RAZOBIN** and get emergency help if you have any of these signs of a severe allergic reaction: difficulty breathing; swelling of your face, lips, tongue or throat.
- Tell your doctor if you develop diarrhoea either during or after taking **RAZOBIN**.
If it becomes severe or persistent, or contains blood or mucus, you should tell your doctor immediately. This may be a sign of a serious side-effect that affects the bowel. You may need urgent medical care.

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- During long-term treatment, your doctor may want to take routine blood tests to monitor your kidney function, liver function and levels of blood cells.
- Tell your doctor immediately if you notice that you are bleeding or bruising more easily than normal.
- Tell your doctor if you develop symptoms of a new infection.
- If you receive doses that are higher than those recommended, you may experience seizures (convulsions).
- Tell your doctor if you are on a low sodium (salt) diet – **RAZOBIN** contains sodium.
- Tell your doctor if you have low levels of potassium in your blood or if you are taking diuretics (for heart problems or high blood pressure) or medicines for cancer. Your doctor might take a blood sample from time to time to test the levels of potassium in your blood.
- Tell your doctor if you have kidney problems, or if you receive haemodialysis treatment. Your doctor may check how well your kidneys are working before he gives you this medicine and adjust the dose to suit you.
- **RAZOBIN** may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using **RAZOBIN**.
- **RAZOBIN** can cause interference in some tests for glucose in urine. Penicillins which are excreted in urine can cause a false-positive result. The doctor will request a test which is not affected by penicillins.

Haemophagocytic lymphohistiocytosis (haemophagocytic syndrome):

Haemophagocytic lymphohistiocytosis may occur. Tell your doctor if any abnormalities such as fever, swollen glands, feeling weak, feeling lightheaded, shortness of breath, bruising, or skin rash, are observed.

Administration of **RAZOBIN** should be discontinued, and appropriate measures should be taken.

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Pregnancy and Breast-feeding:

Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding your baby.

- The safety of **RAZOBIN** during pregnancy and breast-feeding has not been established.

If you are pregnant or breast-feeding your baby receiving **RAZOBIN**, please consult your doctor, pharmacist or other health care professional for advice before taking **RAZOBIN**.

Driving and using machinery:

There is no information to show that **RAZOBIN** affects the ability to drive a car or operate machinery.

Taking other medicines with RAZOBIN:

Always tell your healthcare professional if you are taking any other medicine:

(This includes complementary or traditional medicines.)

- Medicines for gout (probenecid)
- Tobramycin, an antibiotic
- Aminoglycoside antibiotics
- Preparations for thinning blood (e.g warfarin, heparin) – Your doctor may want to monitor you blood clotting time more frequently if you are receiving anticoagulant treatment in combination with **RAZOBIN**.
- Methotrexate, used to treat cancer, rheumatoid arthritis and other inflammatory conditions – Piperacillin may decrease the removal of methotrexate from the body, increasing the risk of its side-effects. Your doctor may want to monitor the amount of methotrexate in your blood if you are receiving methotrexate treatment in combination with this medicine.
- Vecuronium, a muscle relaxant used in surgery.

If you are using any of these medicines, you may not be able to take **RAZOBIN**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

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4. HOW TO RECEIVE RAZOBIN

- A doctor or nurse in hospital will give **RAZOBIN** to you. It will usually be given to you as a slow injection into a vein over 30 minutes.
- The usual adult and juvenile dose of **RAZOBIN** is 4/0.5 g given every 8 hours.
- Children with infections in or around the abdomen:
- The length of time you will be given **RAZOBIN** depends on the type and severity of your infection. It should be given for at least five days, and for 48 hours after all signs of illness and fever have gone.
- If you have kidney problems, your doctor may need to adjust the dose of **RAZOBIN** or how often it is given.

If you have the impression that the effect of **RAZOBIN** is too strong or too weak, talk to your doctor.

If you receive more RAZOBIN than you should:

Since a healthcare professional will administer **RAZOBIN**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Overdose symptoms may include nausea, vomiting, diarrhoea or seizures (convulsions).

If you missed a dose of RAZOBIN:

Your medication will usually be given to you by a healthcare professional. If you think you may have missed a dose, please tell your doctor or nurse.

5. POSSIBLE SIDE-EFFECTS

RAZOBIN can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side-effects:

- Diarrhoea that is watery or bloody.

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- Easy bruising or bleeding, nose bleeds.
- Widespread redness of the skin, or severe peeling of the skin.
- Seizures (convulsions).
- Fever, chills, sore throat, or other signs of infection.
- Anaemia (tiredness, being short of breath and looking pale).
- Inflammation of the wall of a vein with a blood clot forming in the affected segment of vein (pain in the part of the body affected, skin redness, swelling in the part of the body affected, warmth and tenderness over the vein).

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:

- Thrush, headache; difficulty sleeping; muscle pain and weakness; hallucinations; dry mouth; pain, swelling, warmth or redness around the site of injection; flushing; nausea (queasiness, feeling that one is about to vomit); diarrhoea; vomiting; constipation; indigestion; inflammation of the mouth; abdominal pain; skin rash; eczema; itching; hives; joint pain; increased sweating; fever; tiredness; swelling due to retained fluid; increased heart rate.
- Unwanted effects of **RAZOBIN** that you may not be aware of whilst receiving your medicine include low blood pressure (seen as dizziness on standing), inflammation of the veins (swelling or redness along a vein which is extremely tender when touched), changes in the number of red or white blood cells or platelets, or the levels of potassium, glucose or protein in your blood, increases in levels of liver enzymes or bilirubin in the blood, changes in liver function (causing yellowing of the whites of your eyes or skin, itchy skin, darker urine and paler stools), changes in kidney function.

Not all side-effects reported for **RAZOBIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **RAZOBIN**, please consult your doctor, pharmacist or other health care professional for advice.

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6. STORING AND DISPOSING OF RAZOBIN

Dry powder: Vials containing sterile **RAZOBIN** dry powder may be stored at controlled room temperature (at or below 25 °C). Keep the vial in the outer carton until required for use.

Solutions: Vials containing the reconstituted solution should be used immediately or stored at 2-8 °C for not more than 24 hours.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C and 48 hours at 2 – 8 °C. **RAZOBIN** contains no preservatives therefore reconstitution/dilution should take place in controlled and validated aseptic conditions.

RAZOBIN is for single use only. Any unused portion of the reconstituted/diluted solution must be discarded (disposed of).

RAZOBIN is usually stored and handled by a healthcare provider. If you are using **RAZOBIN** at home, store **RAZOBIN** as directed by your pharmacist or healthcare provider.

Store all medicines out of the reach and sight of children.

7. PRESENTATION OF RAZOBIN

RAZOBIN 2:

30 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm violet coloured PP disc.

Pack size: Single vial packed in printed carton with a package insert. Each vial

contains piperacillin sodium and tazobactam sodium cryodesiccated powder for injection equivalent to piperacillin 2, 0 g and tazobactam 0, 25 g.

RAZOBIN 3:

30 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm light blue coloured PP disc.

Pack size: Single vial packed in printed carton with a package insert. Each vial contains piperacillin sodium and tazobactam sodium cryodesiccated powder for injection equivalent to piperacillin 3, 0 g and tazobactam 0,375 g.

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RAZOBIN - 4:

48 mL clear, colourless, tubular glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm red coloured PP disc.

Pack size: Single vial packed in printed carton with a package insert. Each vial contains piperacillin sodium and tazobactam sodium cryodesiccated powder for injection equivalent to piperacillin 4, 0 g and tazobactam 0, 5 g.

8. IDENTIFICATION OF RAZOBIN

A white to off – white cryodesiccated powder. When reconstituted, a light yellow coloured, clear solution free from visible particulate matter is formed.

9. REGISTRATION NUMBER/REFERENCE NUMBER

RAZOBIN 2: 44/20.1.1/0080

RAZOBIN 3: 44/20.1.1/0081

RAZOBIN 4: 44/20.1.1/0082

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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