

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking MEDAZINE INJECTION.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MEDAZINE INJECTION 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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MEDAZINE 1 g INJECTION (Powder for injection)

MEDAZINE 2 g INJECTION (Powder for injection)

Cefoxitin sodium.

1. WHAT MEDAZINE INJECTION CONTAINS

The active substance is cefoxitin.

MEDAZINE 1 g INJECTION:

Each vial contains cefoxitin sodium equivalent to cefoxitin 1 g.

MEDAZINE 2 g INJECTION:

Each vial contains cefoxitin sodium equivalent to cefoxitin 2 g.

2. WHAT MEDAZINE INJECTION IS USED FOR

MEDAZINE INJECTION is an antibiotic used to treat many kinds of infections sensitive to MEDAZINE INJECTION.

3. BEFORE MEDAZINE INJECTION IS ADMINISTERED TO YOU

Do not receive MEDAZINE INJECTION:

- If you have ever had an allergic reaction to cefoxitin or to a cephalosporin antibiotic.
- If you have ever had an allergic reaction to penicillins or any other betalactam class of antibiotics, or any of the other ingredients of the product.

Take special care with MEDAZINE INJECTION:

- Before using MEDAZINE INJECTION, tell your doctor if you are allergic to cephalosporins, or to penicillins, or if you have any other medicine allergies.
- Antibiotic medicines can cause diarrhoea, which may be a complication. If you have developed persistent diarrhoea that is watery or has blood in it or is severe, call your doctor.
- Tell your doctor if you have kidney problems. Your doctor may need to reduce your dosage.
- This medication can cause you to have unusual results with certain lab tests, including tests to check for glucose (sugar) in the urine. Make sure laboratory personnel and all your doctors know that you are using MEDAZINE INJECTION.

Pregnancy and Breast-feeding:

The safety of MEDAZINE INJECTION during pregnancy and breast-feeding has not been established.

If you are pregnant or breast-feeding your baby while receiving MEDAZINE INJECTION, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with MEDAZINE INJECTION:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MEDAZINE INJECTION** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE MEDAZINE INJECTION

- MEDAZINE INJECTION will be given as an injection at your doctor's office, hospital, or clinic.
- This medication may be given by injection into a muscle or vein or as directed by your doctor.
- Since a health care professional will administer MEDAZINE INJECTION, he/she will control the dosage. However in the event for an over dosage your doctor will manage the over dosage.

If you forget to take MEDAZINE INJECTION:

- 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

MEDAZINE INJECTION 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 or severe
- Fever, extreme redness of the skin, scaling, itching, chills
- Feeling light-headed, fainting
- Swelling, pain, or irritation where the injection was given
- Fever, chills, body aches, sore mouth or throat
- Urinating less than usual or not at all
- Easy bruising or bleeding, unusual weakness
- Jaundice (yellowing of the eyes or skin)

Other reported side-effects include:

- Feeling sick (nausea), vomiting, diarrhoea

If any of these side-effects persist, or are troublesome, see your doctor or pharmacist.

Not all side-effects reported for MEDAZINE INJECTION are included in this leaflet. Should your general health worsen while taking MEDAZINE INJECTION, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF MEDAZINE INJECTION

Dry Powder: Store below 25 °C (room temperature).

Solutions: Reconstituted solutions must be used within 24 hours if stored at room temperature (25 °C) or in the refrigerator (at 2 - 8 °C).

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

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

7. PRESENTATION OF MEDAZINE INJECTION

MEDAZINE 1 g INJECTION:

20 ml clear transparent glass moulded vial fitted with grey bromo butyl rubber stopper and sealed with black colour aluminium flip off seal.

Pack sizes: 1's: Each printed carton contains one vial.

10's: Each printed carton contains ten vials.

MEDAZINE 2 g INJECTION:

20 ml moulded clear transparent glass vial fitted with grey bromo butyl rubber stopper and sealed with dark pink colour aluminium flip off seal.

Pack sizes: 1's: Each printed carton contains one vial.

10's: Each printed carton contains ten vials.

8. IDENTIFICATION OF MEDAZINE INJECTION

A white to yellow powder. After reconstitution, a colourless to light amber solution is produced.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS

MEDAZINE 1 g INJECTION 44/20.1.1/0312

MEDAZINE 2 g INJECTION 44/20.1.1/0313

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

Date of registration:

19 April 2013

Date of revision:

29 July 2022