TorbayPharmaceuticals

Package Leaflet: Information for the user
Metaraminol 10mg/mL Solution for Injection or Infusion
Metaraminol Tartrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- **Keep this leaflet. You may need to read it again.**
- **A nurse or doctor will give you the injection.**
- **If you have any further questions, ask your doctor, nurse or pharmacist.**
- **If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet:

1. What Metaraminol 10mg/mL Solution for Injection or Infusion is and what it is used for

The active substance Metaraminol Tartrate belongs to a group of medicines called vasopressors which work by narrowing the blood vessels causing blood pressure to rise.

It is used to:

- Raise low blood pressure to normal levels in an emergency situation.

2. What you need to know before you use Metaraminol 10mg/mL Solution for Injection or Infusion

You will be given this medicine in hospital by a doctor or nurse.

Do not use this medicine:

- With cyclopropane or halothane (anaesthetics) unless your doctor sees a clinical need to do so.
- If you are allergic to metaraminol tartrate or any of the other ingredients in this medicine (listed in section 6).

Warnings and Precautions

Talk to your doctor, nurse of pharmacist before using Metaraminol 10mg/mL Solution for Injection or Infusion if you have:

- Liver disease
- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes mellitus
- A history of malaria

Children

Do not use this medicine in children below the age of 12 years.

Other Medicines and Metaraminol 10mg/mL Solution for Injection or Infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important if you are taking:

- Digitalis medicines (such as digoxin) which may cause an irregular heartbeat.
- Monoamine oxidase inhibitors which may increase the effect of Metaraminol.

Pregnancy, breast-feeding and fertility

The effects of this medicine on fertility and the unborn baby are unknown. It is not known whether this medicine is present in breast milk. You will only be given this medicine if your doctor sees the clinical need to do so in an emergency situation.

Metaraminol 10mg/mL Solution for Injection or Infusion contains Sodium Metabisulfite and Sodium Chloride

This medicine contains

- Sodium - there is less than 1mmol of sodium (23mg) per 10mg/mL ampoule that is to say essentially 'sodium free'.
- Sodium metabisulfite - it is a preservative which may rarely cause severe hypersensitivity reactions and bronchospasm. It may also cause skin reactions if spilt on the skin.

3. How to use Metaraminol 10mg/mL Solution for Injection or Infusion

A nurse or doctor will give you this medicine.

The recommended dose is:

In the case of an emergency this medicine is given by direct injection into a vein, followed by an infusion into a vein. The dose will be adjusted by your doctor, but the usual dose is between 0.5mg and 5mg injected into the vein, followed by an infusion of 15 - 100 mg in 500 mL Sodium Chloride Injection or Dextrose 5% Injection.

Continue overleaf

Additional information for Healthcare Professionals
(as stated on the Summary of Product Characteristics)

Therapeutic indications

For the treatment of acute hypotension due to loss of vasoconstrictor tone as may occur during spinal anaesthesia and as an adjunct to accepted remedial procedures.

Posology and method of administration

Method of Administration

For intravenous use.

Posology

Direct intravenous injection in grave emergencies: 0.5 - 5 mg (0.05 - 0.5 mL), followed by an infusion of 15 - 100 mg (1.5 - 10 mL) in 500 mL of infusion liquid.

Particular care should be taken to use the correct dose when injecting undiluted Metaraminol.

Continued from overleaf

If you are given more Metaraminol 10mg/mL Solution for Injection or Infusion than you should

It is unlikely that you will receive too much because this medicine will be given to you in hospital. You will be carefully monitored by your doctor for symptoms or severely high blood pressure (see symptoms in Section 4 Possible Side Effects).

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience:

- Sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), feeling that you are going to faint (symptoms of a severe hypersensitivity reaction).
- Pain and/or swelling at the injection site.

The following symptoms may be due to severely high blood pressure. Tell your doctor immediately if you experience:

- Headaches
- High blood pressure (hypertension)
- Slow or irregular heartbeat
- Shortness of breath
- Feeling sick
- Chest pain
- Abscesses

Tell your doctor as soon as possible if you experience:

- Cold extremities
- Pain in the extremities

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: Website: www.mhra.gov.uk/yellowcard or Search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Metaraminol 10mg/mL Solution for Injection or Infusion

- Keep this medicine out of the sight and reach of children.
- This medicine has an expiry date printed on the ampoule and carton. Do not use this medicine after the expiry date. The expiry date refers to the last day of the month. Before use the doctor or nurse will check the medicine has not passed this date and that the medicine does not show any sign of deterioration.
- After the expiry date return any unused medicine to a pharmacy.
- Do not throw away any medicines via waste water. These measures will help to protect the environment.
- Only use this medicine if it is particle free.
- This medicine is for single use only.
- Store this medicine at 25°C or below. If diluted in a sterile environment, the medicine can be stored for 48 hours between 2 to 8°C.

6. Contents of the pack and other information

What Metaraminol 10mg/mL Solution for Injection or Infusion contains

The active substance is Metaraminol Tartrate (1.9% w/v), which is equivalent to 1% w/v (10mg/mL) Metaraminol.

The other ingredients are: Sodium Chloride, Sodium Metabisulfite (E223) and Water for Injections.

What Metaraminol 10mg/mL Solution for Injection or Infusion looks like and contents of the pack:

This medicine is a clear, colourless solution in a 1 mL glass ampoule. This medicine is packed into cartons containing 10 ampoules.

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last revised in: October 2023
PL 56021/0011 PIL/11/5

Intravenous Infusion: 15 - 100 mg (1.5 - 10.0 mL) in 500 mL Sodium Chloride Injection or Dextrose 5% Injection, adjusting the rate of infusion to maintain the blood pressure at the desired level. Higher concentrations of Metaraminol have been used when appropriate to the circumstances.

Children: Metaraminol should not be used in children under 12 years of age.

Use in the elderly: The dosage may not require modification for elderley patients; however, geriatric patients may be more sensitive to sympathomimetic agents, therefore particular caution should be taken in this age group.

Incompatibilities

Metaraminol must not be mixed with the following medicinal products due to their additive incompatibilities:

Amphotericin B	Dexamethasone
Prednisolone	Erythromycin
Hydrocortisone	Methicillin
Penicillin G	Thiopental