TorbayPharmaceuticals

Package Leaflet: Information for the user
Metaraminol 0.5mg/mL Solution for Injection
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 0.5mg/mL Solution for Injection is and what it is used for

Metaraminol 0.5mg/mL Solution for Injection contains the active substance Metaraminol Tartrate and 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 0.5mg/mL Solution for Injection

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

Do not use this medicine:
- If you are allergic to metaraminol tartrate or any of the other ingredients in this medicine (listed in section 6).
- With cyclopropane or halothane (anaesthetics) unless your doctor sees a clinical need to do so.

Warnings and Precautions
Talk to your doctor, nurse or pharmacist before using Metaraminol 0.5mg/mL Solution for Injection if you have:
- Liver disease
- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes mellitus
- A history of malaria

Children
This medicine is not recommended for use in children below the age of 12 years.

Other medicines and Metaraminol 0.5mg/mL Solution for Injection
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 action of metaraminol.

Pregnancy, breast-feeding and fertility
The effects of this medicine on the unborn baby is 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 0.5mg/mL Solution for Injection contains sodium metabisulfite and sodium chloride
This medicine contains
- Sodium metabisulfite – a preservative which may rarely cause severe hypersensitivity reactions and bronchospasm. It may also cause skin reactions if spilt on the skin.
- Sodium – there is less than 1mmol sodium (23mg) per 0.5mg/mL, that is to say essentially 'sodium - free'.

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. Metaraminol 0.5mg/mL Solution for Injection should not be diluted before use: it is supplied ready to use.

Posology
Direct intravenous injection in grave emergencies: 0.5 - 5 mg (1 – 10 mL), which may be followed by an infusion of 15 – 100mg (30 – 200mL of metaraminol 0.5mg/mL solution for injection) titrated to clinical effect. In the event of escalating vasopressor requirement, the more concentrated metaraminol 10mg/mL solution for injection or infusion can be administered as 15 – 100mg in 500 mL of infusion liquid. When vasoactive drug support is no longer indicated, the infusion should be gradually decreased. Abrupt withdrawal can result in acute hypotension.

3. How to use Metaraminol 0.5mg/mL Solution for Injection

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, which may be followed by an infusion into a vein. The dose will be adjusted by your doctor, but the usual dose is between 0.5 – 5mg (1 – 10mL) injected into the vein, followed by an infusion of 15 – 100mg (30 – 200mL of metaraminol 0.5mg/mL solution for injection). Metaraminol 0.5mg/mL Solution for Injection is already diluted and ready to use. It should be used without prior dilution.

If you are given more Metaraminol 0.5mg/mL Solution for Injection 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 0.5mg/mL Solution for Injection

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton. 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.
- This medicinal product does not require any special storage condition.

6. Contents of the pack and other information

What Metaraminol 0.5mg/mL Solution for Injection contains

- The active substance is metaraminol tartrate (0.095%w/v), which is equivalent to 0.05%w/v (0.5mg/mL) metaraminol.
- The other ingredients are: sodium chloride, sodium metabisulfite (E223) and Water for Injections.

What Metaraminol 0.5mg/mL Solution for Injection looks like and contents of the pack:

This medicine is a clear, colourless solution in a 5 mL or 10 mL glass ampoule. This medicine is packed into cartons containing 10 ampoules.

Marketing Authorisation Holder and Manufacturer:

Torbay Pharmaceuticals Limited, Wilkins Drive, Paignton, Devon, TQ4 7FG, UK
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Children: The safety and efficacy of Metaraminol 0.5mg/mL Solution for Injection in children under 12 years of age has not been established. No data are available.

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

Incompatibilities

Metaraminol 0.5mg/mL Solution for Injection must not be mixed with other medicinal products.