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 is and what it is used for
2. What you need to know before you use Metaraminol
3. How to use Metaraminol
4. Possible side effects
5. How to store Metaraminol
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1. What Metaraminol 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

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

Do not use metaraminol

- if you are allergic to metaraminol tartrate or any of the other ingredients of 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 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
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 10mg/ml Solution for Injection or Infusion 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 – contains less than 1mmol sodium (23mg) per 10mg/ml ampoule, that is to say essentially 'sodium - free'.

3. How to use Metaraminol

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.
The usual dose is between 0.5 – 5mg injected into the vein, followed by an infusion of 15 – 100mg in 500ml Sodium Chloride Injection or Glucose 5% Injection.
Metaraminol 10mg/ml Solution for Injection or Infusion may be used undiluted or diluted.

If you are given more metaraminol than you should use
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).
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

The following information is intended for healthcare professionals only:
(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.

Method of Administration
For intravenous use.
Metaraminol 10mg/ml Solution for Injection or Infusion may be used undiluted or diluted.

Posology
Direct intravenous injection in grave emergencies: 0.5 - 5mg (0.05 - 0.5ml), followed by an infusion of 15 - 100mg (1.5 - 10ml) in 500ml of infusion liquid. Particular care should be taken to use the correct dose when injecting undiluted metaraminol.

Intravenous Infusion: 15 - 100mg (1.5 - 10.0ml) in 500ml Sodium Chloride 0.9% Injection or Glucose 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.
When vasoactive drug support is no longer indicated, the infusion should be gradually decreased. Abrupt withdrawal can result in acute hypotension.

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 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

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 as EXP.
The expiry date refers to the last day of that 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.

Do not throw away any medicines via wastewater. These measures will help protect the environment.

Only use this medicine if it is particle free.
This medicine is for single use only.
Store below 25°C.
If diluted in a sterile environment, the medicine can be stored for up to 48 hours at ambient temperature 20-22°C or 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 1.0 %w/v (10mg/ml) metaraminol.

The other ingredients are: sodium chloride, sodium metabisulfite (E223) and water for injections.
May contain traces of sodium hydroxide or hydrochloric acid (for pH adjustment).

What Metaraminol 10mg/ml Solution for Injection or Infusion looks like and contents of the pack
This medicine is a clear, colourless solution free of particles.
It is available in a 1ml clear glass ampoules with a purple coloured spot and one-point-cut score, packed into cartons containing 10 ampoules.

Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North, Wrexham LL13 9UF, UK
Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham LL13 9UF, UK

Other formats
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only). Please be ready to give the following information:

Product name	Reference number
Metaraminol 10mg/ml Solution for Injection or Infusion	PL 29831/0740

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 08/2022

Children: The safety and efficacy of metaraminol 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
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products except Sodium Chloride 0.9% Solution or Glucose 5% Solution.

In use shelf life:
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 48 hours at 2 to 8°C unless opening has taken place in controlled and validated aseptic conditions.

After diluton for infusion the in use shelf life is 48 hours when stored in PVC free infusion bags either at ambient temperature 20-22°C or between 2-8°C in an intravenous infusion of Sodium Chloride 0.9% Solution or Glucose 5% Solution.

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