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.
- 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

This medicine contains the active substance Metaraminol tartrate, which belongs to a group of medicines called "vasopressors". These medicines work by narrowing the blood vessels causing blood pressure to rise.

This medicine is used to treat low blood pressure that can occur during spinal or epidural anaesthesia.

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).
- if you are being given certain types of anaesthetics (halothane or cyclopropane), unless your doctor sees a clinical need to do so.
- if you have low blood pressure caused by low blood volume.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Metaraminol if you suffer from or have suffered in the past from any of the following conditions:
- 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

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.
- Anaesthetics such as cyclopropane or halothane.
- Oxytocin, a drug used to prevent or control bleeding after delivery of your baby.

Pregnancy, breast-feeding and fertility

Pregnancy

The effects of this medicine on 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.

Driving and using machines

This medicine is not expected to affect your ability to drive or use machines.

Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per 10mg/ml ampoule, that is to say essentially 'sodium free'.

3 How to use Metaraminol

This medicine will be given to you in a hospital as an injection into a vein or diluted before use and given with fluid into a vein.

Your doctor will decide on the correct dosage for you and how and when the medicine will be given.

Additional information for healthcare professionals (as stated on the summary of product characteristics):

Therapeutic indications

For 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 - 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 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 elderly patients; however, geriatric patients may be more sensitive to sympathomimetic agents, therefore particular caution should be taken in this age group.

Direct Intravenous injection (in grave emergencies)

The initial dose is 0.5 – 5mg metaraminol, followed by an infusion of 15 – 100mg metaraminol, in a diluent, made up to a total volume of 500ml.

Intravenous infusion:

15 – 100mg in 500ml Sodium Chloride Injection or Glucose 5% Injection. Higher concentrations of Metaraminol have been used when appropriate to the circumstances.

If you are given too much Metaraminol

In the event you are given too much Metaraminol, you may experience high blood pressure accompanied by a headache, a tight feeling in the chest, nausea, vomiting, euphoria, sweating, fluid in the lungs, increased or decreased heart rate, irregular heartbeat, heart attack, heart failure, or convulsions (fits).

Tell your doctor immediately if you feel unwell. Treatment with this medicine may subsequently be stopped, and if needed, an antidote will be administered by medical staff.

4 Possible side effects

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

The frequency of possible side effects are listed below.

Tell your doctor immediately if you experience:

Very Common
(may affect more than 1 in 10 people):

- Headache
- High blood pressure

Rare (may affect up to 1 in 1,000 people):

- Abscess or peeling skin at the site of injection, or an area where the tissue around the injection site dies

Not known
(Frequency cannot be estimated from available data):

- Fatal changes in heart rhythm in patients suffering from liver cirrhosis
- Changes in heartbeat including slower or faster heart rates or palpitations
- Reduced blood supply to the arms and legs (including hands and feet)
- Feeling sick

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 ampoule and the carton after "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.

After the expiry date return any unused medicine to a pharmacy.

Do not throw away any medicines via waste water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the enviroment.

Only use this medicine if it is particle free.

This medicine is for single use only.

Store this medicine at 25°C or below. Do not freeze. If diluted in a sterile environment, the medicine can be stored for 24 hours between 2 to 8°C.

Store ampoules in the outer carton in order to protect from light.

6 Contents of the pack and other information

What Metaraminol 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, Citric acid monohydrate (pH adjuster), Glacial acetic acid, Sodium acetate trihydrate, Disodium edetate and Water for Injections

What Metaraminol looks like and contents of the pack

This medicine is a clear, colourless solution in a 1ml clear glass ampoule.

This medicine is packed into cartons containing 5 ampoules.

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

SALF SpA Laboratorio Farmacologico
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24069 Cenate Sotto (Bergamo)
Italy

This leaflet was last revised in **February 2022**

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Additional information for healthcare professionals (as stated on the summary of product characteristics):

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

After dilution, chemical and physical in-use stability has been demonstrated for 24 hours when the diluted product is stored between 2 to 8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Each ampoule is intended for single use only. If only part of an ampoule is used, the remainder must be discarded.

Handling and disposal

The normal procedures for the proper handling of injectable medicinal products should be adopted.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.