107057

Package leaflet: Information for the user

Metaraminol 0.5 mg/ml, Solution for Injection in pre-filled syringe

(Referred to as "Metaraminol injection" in this leaflet)
Metaraminol tartrate

AGUETTANT

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 or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metaraminol injection is and what it is used for

Metaraminol injection 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 are given Metaraminol injection

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

You should not be given this medicine:
- if you are allergic to metaraminol or any of the other ingredients in this medicine (listed in section 6).
- with cyclopropane or halothane (inhaled anaesthetics) unless your doctor sees a clinical need to do so.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Metaraminol injection:
- if you have liver disease
- if you have heart disease
- if you have high blood pressure
- if you have thyroid disease
- if you have diabetes
- if you have or have ever had malaria

Children and adolescents

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

Other medicines and Metaraminol injection

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is especially important if you are taking:
- anaesthetics that are inhaled such as halothane or cyclopropane;
- digitalis medicines (such as digoxin) which may cause an irregular heartbeat;
- medicines used to treat depression;
- inhibitors of alpha receptors of the sympathetic nervous system that are used to treat hypertension among others;
- oxytocin, a medicine used during labour or delivery;
- ergot alkaloids, a type of medicine used for headache;
- doxapram, a medicine used to treat breathing problems;
- guanethidine and related medicines, used to treat high blood pressure.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
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.

Driving and using machines

Metaraminol injection may affect your ability to drive or operate machines. Ask your doctor about when it would be safe to drive or operate machines.

Metaraminol injection contains sodium

5 ml syringe:
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml syringe, that is to say essentially "sodium-free".
10 ml syringe:
This medicine contains 35.4 mg sodium (main component of cooking/table salt) in each 10 ml syringe. This is equivalent to 1.8 % of the recommended maximum daily dietary intake of sodium for an adult.

The following information is intended for healthcare professionals only:

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

For intravenous use. The pre-filled syringe is not suitable for syringe pump drivers.
Direct intravenous injection in grave emergencies: 0.5 - 5 mg (1 to 10 ml).
Bolus doses should be administered at the minimal efficient dose.
The maximum cumulative dose after repeated direct intravenous injections is 5mg. One direct IV injection should usually not exceed 1mg.
Direct intravenous injection may be followed by an infusion of 15 - 100 mg in 500 mL of infusion liquid, using an appropriate metaraminol formulation and administration.
Metaraminol 0.5 mg/ml solution for injection in pre-filled syringe is not suitable for intravenous infusion.
Metaraminol 0.5 mg/ml, solution for injection should not be diluted before use: it is supplied ready to use in pre-filled syringes.
The contents of the syringe should not be added to infusion fluids.
Metaraminol should be administered under comprehensive hemodynamic monitoring.
In case of extravasation, local administration of an alpha blocker such as Phentolamine may prevent the risk of necrosis.

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.

Please prepare the syringe carefully as follows

The pre-filled syringe is for single patient only. Discard syringe after use. DO NOT REUSE.
The content of an un-opened and un-damaged blister is sterile, and the blister must not be opened until the syringe is ready to be used.
The product should be inspected visually for particles and discoloration prior to administration. Only a clear colourless solution free from particles or precipitates should be used.
The product should not be used if the tamper evident seal on the syringe is broken.
The external surface of the syringe is sterile until the blister is opened.

3. How Metaraminol injection is given

This medicine will be administered by a healthcare professional with appropriate training and relevant experience.
Your doctor will decide the most suitable dosage for your particular case according to your age and medical condition, as well as for the site of injection, and your response to the injection.

If you receive more Metaraminol injection than you should

Since this medicine is administered to you by a trained healthcare professional, it is unlikely that you will be given too much of Metaraminol injection.
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, pharmacist or nurse.

4. Possible side effects

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

Some side effects may be serious. Seek immediately medical help if you experience the following symptoms that may be due to severely high blood pressure:

- Shortness of breath
- Chest pain
- Slow or irregular heart beat
- Headaches
- Feeling sick

Other side effects may include:

<u>Very common (may affect more than 1 in 10 people)</u>
- Headaches
- High blood pressure

<u>Rare (may affect up to 1 in 1,000 people)</u>
- Abscess formation; tissue necrosis; sloughing

<u>Not known (cannot be estimated from the available data)</u>
- Feeling worried, fear, confusion, irritability, change in your personality or the way you feel or think, sweating
- Restlessness, dizziness, insomnia
- Flushing, low blood pressure
- Cold extremities
- Pain in the extremities
- Nausea and vomitting
- Difficulty passing urine

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: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metaraminol injection

Keep this medicine out of the sight and reach of children.
You should not be given this medicine after the expiry date which is stated on the syringe label, blister and carton.
The expiry date refers to the last day of that month.
Your doctor or nurse will check this.
Keep the syringe in its unopened blister until use.
Do not freeze.
Do not use this medicine if you notice visible signs of deterioration.
Any syringe, even partially used, should be discarded appropriately after use. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metaraminol injection contains

The active substance is Metaraminol tartrate:
- Each ml of solution for injection contains 0.5 mg of metaraminol (as tartrate).
- Each 5 ml pre-filled syringe contains 2.5 mg of metaraminol (as tartrate).
- Each 10 ml pre-filled syringe contains 5 mg of metaraminol (as tartrate).

The other ingredients are sodium chloride, hydrochloric acid, and water for injections.

What Metaraminol injection looks like and contents of the pack

Metaraminol injection is a clear colourless solution, in a 5 ml or 10 ml polypropylene pre-filled syringe, individually packaged in a transparent blister pack.

Marketing Authorisation Holder

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1, rue Alexander Fleming
69007 Lyon
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Manufacturer

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Detailed information on this medicine is available on the website of Medicines and Healthcare Products Regulatory Agency (MHRA).

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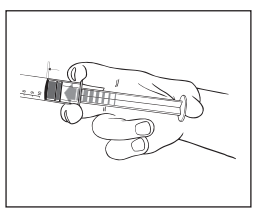
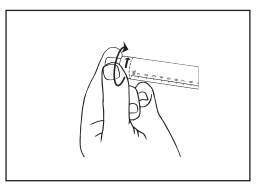
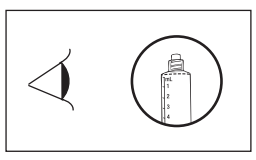
1) Withdraw the pre-filled syringe from the sterile blister.



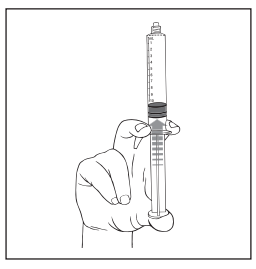
2) Push on the plunger to free the bung.
The sterilisation process may have caused adhesion of the bung to the body of the syringe.



3) Twist off the end cap to break the seal.
Do not touch the exposed luer connection in order to avoid contamination.



4) Check the syringe seal tip has been completely removed. If not, replace the cap and twist again.



5) Expel the air by gently pushing the plunger.

6) Connect the syringe to the vascular access device. Push the plunger slowly to inject the required volume.