Package leaflet: Information for the user

Metaraminol 10 mg/ml Solution for Injection or Infusion

Metaraminol (as tartrate)

Read all of this leaflet carefully before you start taking 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 nurse.
- If you get any side effects, talk to your doctor 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

The name of this medicine is Metaraminol 10 mg/ml Solution for Injection or Infusion. The name is shortened to Metaraminol Injection in the rest of this leaflet.

It contains metaraminol tartrate, which is one of a group of medicines used to treat low blood pressure that can occur during spinal or epidural anaesthesia.

2. What you need to know before you are given Metaraminol 10 mg/ml Solution for Injection or Infusion

You should not be given Metaraminol Injection if:
- you are allergic to metaraminol tartrate or any of the other ingredients of this medicine (listed in section 6) or to sulphites contained in other products, as it may rarely cause severe allergic (hypersensitivity) reactions and difficulty breathing
- you are being given certain types of anaesthetic (halothane or cyclopropane)
- you have low blood pressure that has been caused by low blood volume

Warnings and precautions
Talk to your doctor or nurse before being given Metaraminol Injection.

Your doctor will administer the medicine with care to avoid rapid changes in your blood pressure which can cause fluid build-up in the lungs, irregular heartbeat, or heart failure. If any of these occur, your doctor will take appropriate action.

If it is necessary to administer Metaraminol Injection for a prolonged time, this can cause high blood pressure which continues when this medicine is stopped. Your doctor will treat this if necessary.

The medicine may cause increased urination, leading to dehydration. If this happens you will be given fluid replacement.

Your doctor needs to know **before** you are given Metaraminol Injection if you suffer from or have suffered in the past from any of the following conditions:

- liver disease
- heart problems or chest pains
- high blood pressure
- overactive thyroid
- diabetes
- malaria

Your doctor or nurse will choose the most suitable vein for the injection to be given. If there is any leakage of medicine around the injection site this can cause tissue damage. The injection site will be checked frequently. If leakage occurs you will be given treatment to avoid tissue damage occurring.

Children and adolescents
Metaraminol Injection should not be given to children.

Other medicines and Metaraminol Injection
Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular the following medicines:

- anaesthetics such as cyclopropane or halothane
- a monoamine oxidase inhibitor (used to treat severe depression), such as phenelzine or isocarboxazid
- cardiac glycosides e.g. digoxin, used to strengthen the heart
- oxytocin, a drug used to prevent or control bleeding after delivery of your baby

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 or nurse for advice before you are given Metaraminol Injection. If you are pregnant, it is unlikely that you will be given this medicine unless absolutely necessary. Metaraminol Injection can be given to breast-feeding mothers with caution, although it is not known if the medicine is passed through to the baby in the mother's milk.

Driving and using machines
Metaraminol Injection is not expected to affect your ability to drive or use machines.

Metaraminol Injection contains sodium chloride and sodium metabisulphite
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially "sodium free". If the maximum recommended dose of 100 mg is given, the administered dose will contain 38.3 mg sodium (main component of cooking salt/table salt) in 10 ml of metaraminol solution. This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine also contains sodium metabisulphite (E223) which may rarely cause severe allergic (hypersensitivity) reactions and bronchospasm (difficulty breathing).

3. How Metaraminol 10 mg/ml Solution for Injection or Infusion will be given

This medicine will be given to you in a hospital environment by an experienced doctor.

The dose of the medicine will depend on your condition at the time. Your doctor will know the best dose to use. The medicine is first diluted and is then infused (injected) into a vein. The dose can then be adjusted using a pump according to your response to treatment, with the aim to establish a normal blood pressure. The initial dose is usually 15-100 mg metaraminol.

Whilst receiving Metaraminol Injection, your heart rate, heart rhythm and blood pressure will all be monitored.

Use in children
Metaraminol Injection should not be given to children.

If you are given too much Metaraminol Injection
In the event that you are given too much Metaraminol Injection, you may experience high blood pressure, headache, 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). If this happens, treatment with this medicine will be stopped and, if needed, an antidote will be administered by medical staff.

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.

Some of the side effects can only be detected by your doctor during a physical examination or as a result of other tests that will be carried out before and after your treatment.

The frequency of possible side effects are listed below:

Very common (affects more than 1 patient in 10):
- headache
- high blood pressure

Rare (affects 1 to 10 patients in 10,000):
- 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 heart beat including slower or faster heart rates or palpitations
- reduced blood supply to the arms and legs (including hands and feet)
- feeling sick

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly in Ireland via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. 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.

This medicinal product does not require any special storage conditions.

Your doctor will check that this medicine is not used after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Chemical and physical in-use stability has been demonstrated for 48 hours at 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.

Your doctor will check if the product shows any visible signs of deterioration.

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 1 ml ampoule contains 1 ml of solution containing metaraminol tartrate equivalent to 10 mg metaraminol.

- The other ingredients are sodium metabisulphite (E223), sodium chloride, sodium hydroxide (for pH adjustment), tartaric acid (for pH adjustment) and water for injection.

What Metaraminol Injection looks like and contents of the pack

Metaraminol solution is a clear and colourless liquid. It is supplied in 1 ml colourless glass ampoules and each carton contains 5 ampoules or 10 (2 packs of 5) ampoules (multipack). Not all pack sizes may be marketed.

Marketing Authorisation Holder

Global Harvest Pharmaceuticals (Ireland) Limited,
Georgian House,
12 Patrick Street,
Kilkenny, R95 P573,
Ireland

Manufacturer

GH Pharma (UK) Limited,
12 The Broadway,
St Ives, PE27 5BN,
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland and United Kingdom Metaraminol 10 mg/ml Solution for Injection or Infusion

This leaflet was last revised in 10/2020.

The following information is intended for healthcare professionals only:

Instructions on how to dilute, store and dispose of Metaraminol Injection

Dilution
For intravenous infusion, further dilution is required. Metaraminol Injection should be diluted in 0.9% w/v Sodium Chloride Infusion or 5% w/v Glucose Infusion to give a final concentration of 15-100 mg metaraminol in 500 ml infusion fluid.

In grave emergencies, direct intravenous injection of 0.5-5 mg metaraminol (0.05-0.5 ml metaraminol solution for injection) followed by an infusion of 15-100 mg metaraminol in 500 ml of 0.9% Sodium Chloride Infusion or 5% Glucose Infusion may be administered.

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

Shelf-life after preparing the solution for infusion
Chemical and physical in-use stability has been demonstrated for 48 hours at 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 8ºC, unless dilution has taken place in controlled and validated aseptic conditions.

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.