# Package leaflet: Information for the user

# Metaraminol 10 mg/ml Solution for Injection/Infusion Metaraminol

**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 10 mg/ml Solution for Injection/Infusion is and what it is used for

The name of the medicine is Metaraminol 10 mg/ml Solution for Injection/Infusion. The name is shortened to Metaraminol Injection in the rest of the leaflet. It contains the active ingredient metaraminol (as metaraminol tartrate).

It is used to increase your blood pressure which can drop during spinal anaestheisa or can drop as a reaction to medications or surgical complications.

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

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 tartrate or any of the other ingredients of this medicine (listed in section 6) including sulfites that may cause an allergic type reaction or an asthmatic episode in certain susceptible people.
- if you are being given cyclopropane or halothane anaesthesia unless your doctor sees a clinical need to do so
- if 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 the medicine is stopped. Your doctor will treat this if necessary.

This medicine may result in a diuretic effect, which increases urination, and may affect electrolyte levels. 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 ever suffered from any of the following conditions:

- Liver disease or injury
- Heart disease
- High blood pressure
- Thyroid disease
- 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 damage. The injection site will be checked frequently. If leakage occurs you will be given treatment to avoid tissue damage occurring.

### Children and adolescents

Do not use this medicine in children below the age of 12 years.

### Other medicines and Metaraminol

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 such as cyclopropane or halothane.
- Digitalis medicines (such as digoxin) which may cause an irregular heartbeat
- A monoamine oxidase inhibitor (used to treat severe depression), such as phenelzine or isocarboxazid
- Oxytocin, a drug used to prevent or control bleeding after delivery of your baby

These medicines may be affected by metaraminol or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

### 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 being given this medicine.

If you are pregnant, it is unlikely that you will be given this medicine, unless the doctor sees the clinical need to do so in an emergency situation.

It is not known whether this medicine is passed through to the baby in the mother's breast milk. Caution should be exercised if this medicine is given to a breast-feeding mother.

### 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 metabisulfite

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.
This medicine also contains sodium metabisulfite (E223), a preservative which may rarely cause severe allergic (hypersensitivity) reactions and difficulty breathing (bronchospasm).

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

Metaraminol Injection 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.

**Direct Intravenous injection (in grave emergencies)**

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

**Intravenous infusion**

15 – 100 mg metaraminol in 500 ml Sodium Chloride Injection or Glucose 5% Injection.

Higher concentrations of Metaraminol have been used when appropriate to the circumstances.

**Use in children**

Do not use this medicine in children below the age of 12 years.

**If you are given too much Metaraminol Injection**

In the event you are given too much Metaraminol Injection, 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 heart beat, 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** (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

**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 in the UK 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 10 mg/ml Solution for Injection/Infusion

Keep this medicine out of the sight and reach of children.

Metaraminol Injection should only be given to you in a hospital. The hospital is responsible for storing it correctly.

Your doctor or nurse will check the expiry date has not passed before giving you this medicine.

## 6. Contents of the pack and other information

**What Metaraminol 10 mg/ml Solution for Injection/ Infusion contains:**

- The active substance is Metaraminol (as metaraminol tartrate). Each vial contains 1 ml of Metaraminol 10 mg/ml Injection
- The other ingredients: sodium chloride, sodium metabisulfite (E223), tartaric acid, sodium hydroxide and Water for Injections.

**What this medicine looks like and contents of the pack**

A clear, colourless to slightly yellow/pink solution in a 2 ml clear glass vial sealed with a grey rubber stopper and aluminium seal with a purple plastic flip off cap.

It is supplied in a carton containing 10 vials.

**Marketing Authorisation Holder**

Phebra Limited
24-25 New Bond Street, 1st Floor, London,
England, W1S 2RR United Kingdom

**Manufacturer**

Flexipharm Austrading Limited
ATI House, 6 Boston Drive, Bourne End,
Buckinghamshire, SL8 5YS United Kingdom

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**The following information is intended for medical or healthcare professionals only:**

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

**Dilution**

For intravenous infusion, 15 – 100 mg metaraminol in 500 ml Sodium Chloride Injection or Glucose 5% Injection.

Higher concentrations of Metaraminol may be used when appropriate to the circumstances.

**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 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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

**Handling and disposal**

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

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