Rx Adrenaline Bitartrate Injection I.P.

ADR Injection

Read all of this leaflet carefully before you are given 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.

The name of your medicine is Adrenaline Bitartrate Injection IP. It will be referred to as ADR Injection for ease hereafter.

What is in this leaflet

1. What ADR Injection is and what it is used for
2. What you need to know before you are given ADR Injection
3. How ADR Injection will be given to you
4. Possible side effects
5. How to store ADR Injection
6. Contents of the pack and other information

1. WHAT ADR INJECTION IS AND WHAT IT IS USED FOR

Adrenaline belongs to a class of drugs called sympathomimetic agents. ADR Injection may be used to rapidly relieve severe allergic reactions to drugs or other substances causing allergy. It may also be used in the emergency treatment of shock due to a severe allergic reaction.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ADR INJECTION

You should not be given ADR Injection:

- If you are allergic to adrenaline, or to any of the other ingredients of this medicine (listed in section 6).
- When you are in labour
- If you have severe heart disease particularly if it is associated with an increased heart rate
- If you are suffering from any infection, disease or tumour of the brain
- If you have atherosclerosis which is a narrowing, and hardening of the body's blood vessels (your doctor will advise you).

ADR injection should not be used in areas such as fingers, toes, ears, nose or penis, as the blood supply to these areas might become inadequate

Warnings and precaution

Talk to your doctor or nurse before you are given ADR Injection if:

- You are elderly
- You have problems with your kidneys
- You suffer from any heart problem, particularly if it affects the heart rate or if you suffer from chest pain
- You have problems with your brain e.g. stroke, brain damage or blood vessel disease
- You have an overactive thyroid, diabetes or glaucoma (high pressure in the eye)
- You have phaeochromocytoma (a tumour on the adrenal gland)
- You have low blood levels of potassium or high blood levels of calcium
- You have a tumour on your prostate gland or kidney disease
- You are in shock or have lost a lot of blood
- You are going to have a surgery under general anaesthesia
- You are suffering from high blood pressure.

Other medicines and ADR Injection

Tell your doctor or pharmacist if you are taking, or recently taken or might take any other medicines.

A large number of drugs can interact with ADR Injection which can significantly alter their effects. These drugs include:

- Monoamine oxidase inhibitors (MAOI) or tricyclic antidepressants both used for depression
- Guanethidine, used for the rapid control of blood pressure
- Diuretics ("water tablets")
- Inhaled general anaesthetics, such as halothane
- Medicines to raise or lower your blood pressure including betablockers, e.g. propranolol, atenolol, bisoprolol, phentolamine
- Anti-diabetic drugs like insulin or oral hypoglycaemic agents (e.g. glipizide)
- Aminophylline and theophylline (medicines to help you breathe)
- Corticosteroids (medicines used to treat inflammatory conditions in your body such as asthma or arthritis)
- Antihistamines (for example: diphenhydramine), used for the treatment of allergies
- Medicines used to treat mental illness like chlorpromazine, pericyazine or fluphenazine
- Medicines used to treat an underactive thyroid gland
- Oxytocin (used to induce labor at term and to control bleeding after delivery)
- Any cough or cold remedies (sympathomimetics).

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 pharmacist for advice before using this medicine.

Adrenaline should only be used during pregnancy and breast-feeding if considered essential by your doctor.

Driving and using machines: You should not drive or use machinery if you are affected by the administration of ADR Injection.

ADR Injection contains sodium metabisulphite

This medicine contains sodium metabisulphite, a preservative. This may rarely cause severe allergic (hypersensitivity) reactions and wheezing. This medicinal product contains less than 1mmol sodium (23mg) per dose (essentially 'sodium-free').

3. HOW ADR INJECTION WILL BE GIVEN TO YOU

The recommended dose is 500 micrograms (0.5ml of adrenaline 1/1000). If necessary, this dose may be repeated several times at 5-minute intervals.

Adrenaline may be injected either into a muscle or into the tissue just beneath the skin. It will be administered by a trained healthcare professional. Your doctor will decide the most suitable dosage for your particular case according to your age and physical circumstances

Use in Children

The following doses of adrenaline 1/1,000 are recommended:

Age	Dose
Over 12 years	0.5 mg IM (0.5ml 1:1000 solution)
6 - 12 years	0.3 mg IM (0.3ml 1:1000 solution)
6 months - 6 years	0.15 mg IM (0.15ml 1:1000 solution)
Under 6 months	0.01mg/kg IM (0.01ml/kg 1:1000 solution)

If necessary, these doses may be repeated at 5-15 -minute intervals according to blood pressure, pulse and respiratory function.

A small volume syringe should be used.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

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

If you experience any of these following side effects, stop taking this medicine and report to a doctor immediately:

- Allergic reactions although serious allergic reactions are rare
- Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).
- Symptoms of chest pain, shortness of breath, nausea or an irregular heartbeat, especially if you are feeling stressed. These can be signs of a condition known as stress cardiomyopathy.

Other side effects

Not known: frequency cannot be estimated from the available data:

• headache • dizziness • feelings of anxiety or fear or restlessness • trembling • insomnia, confusion, irritability • abnormal mood or behaviour • a dry mouth or producing too much saliva • weakness or sweating • changes in the rhythm and speed of the heart • high blood pressure • coldness of the arms or legs • breathlessness • reduced appetite, feeling sick or being sick • repeated injections may damage tissues at the site of the injection • difficulty of not being able to pass water • metabolic acidosis (an imbalance of certain constituents in your blood) may occur • there may be some tissue damage at the site of injection after repeated injections of adrenaline • increase in tremors and rigidity in patients suffering from a condition called Parkinsonian syndrome • bleeding in the head • paralysis of one half of the body • increased sugar levels in the blood • breakdown of fat in the body.

Reporting of side effects

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. You can also report side effects directly via 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 ADR INJECTION

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 carton and ampoule label after "Exp". The expiry date refers to the last day of that month. Do not store above 25°C. Keep the container in the outer carton in order to protect from light. The solution should not be used if it is discoloured in any way. This medicine should not be mixed with any other drugs. The solution must not be stored in contact with metals e.g. needles or metal parts of syringes, as dissolved metal ions may cause swelling at the site of the injection. If only part of an ampoule is used, the remaining solution should be discarded. 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 Adrenaline Injection contains

The active substance is adrenaline. Each ml contains Adrenaline Bitartrate IP Equivalent to Adrenaline 1 mg and excipients in water for injections.

What ADR Injection looks like and contents of pack Adrenaline Injection is a clear colourless, aqueous, sterile solution for injection, available in 1ml glass ampoules, packed in boxes containing 10 ampoules.

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