



MercuryPharma

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Adrenaline (Epinephrine) 1:1,000 Solution for 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 (Epinephrine) 1:1,000 Solution for Injection. It will be referred to as Adrenaline Injection for ease hereafter.

What is in this leaflet

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

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

Adrenaline belongs to a class of drugs called sympathomimetic agent. Adrenaline 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 ADRENALINE INJECTION

You should not be given Adrenaline 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 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).

Adrenaline 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.

Speak to your doctor if one of these applies to you before you are given this medicine.

In an emergency, your doctor may still give you adrenaline even if you suffer from any of the above, as the potential benefit may be greater than the risk.

Warnings and precaution

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

- you are elderly
- 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 tumor on the adrenal gland)
- you have low blood levels of potassium or high blood levels of calcium
- you have a tumor 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 Adrenaline Injection

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

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

- monoamine oxidase inhibitors (MAOI) or tricyclic antidepressants both used for depression
- cardiac glycosides such as digoxin, used for heart failure
- 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
- antidiabetic 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 (e.g. 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).

If you are already taking one of these medicines, speak to your doctor before you receive Adrenaline Injection.

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

Driving and using machines

This is unlikely to be applicable as you will not feel well enough to drive or use machinery. Consult your doctor before considering such action.

Adrenaline 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').

Note: Adrenaline Injection must not be injected into peripheral parts of the body such as fingers, toes, ear lobes, nose or penis. The solution should not be used if it is discolored. It should not be mixed with any other agent.

3. HOW ADRENALINE INJECTION WILL BE GIVEN TO YOU

Adrenaline may be injected into a muscle or into the tissue just beneath the skin. It must be diluted before injection into a vein.

Acute attacks of asthma, allergic reactions and shock due to a severe allergic reaction.

Adults: The usual dose is 0.3 to 0.5mg (0.3 to 0.5ml), injected into a muscle or into the tissue just beneath the skin. If necessary, this can be repeated at 15 to 20 minute intervals for two

doses, then subsequently every 4 hours as required. A dose of 1mg (1ml) can be given as a single injection in severe allergic reactions and in shock due to an allergic reaction.

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.

Use in patients with kidney problems: Adrenaline Injection should be used with caution in patients with kidney problems.

Use in elderly patients: The dosage is the same as for younger adults but caution is required when adrenaline is administered to the elderly.

Cardiopulmonary Resuscitation: as follow-up treatment in cardiopulmonary resuscitation, a dose of 0.3mg (0.3ml) may be injected into the tissue just beneath the skin, after administration of a 1 in 10 000 dilution (containing 0.1mg of adrenaline per ml) into a vein or into the heart.

Cardiac arrest: In the treatment of cardiac arrest, Adrenaline Injection must be diluted with 0.9% w/v sodium chloride to a 1 in 10 000 solution (1mg in 10ml) solution before intravenous administration. Following dilution, adrenaline (as a 1 in 10 000 solution) may be administered into a vein in a dose of 10ml (1mg).

It will be administered by a trained healthcare professional. Your doctor will decide the most suitable dosage and route of administration for your particular case according to your age and physical circumstances.

If you are given more Adrenaline Injection than you should

This is unlikely as your injection will be administered by a doctor or nurse. If you are concerned about the dose, discuss this with your doctor.

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 everybody 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, dizziness, nausea or an irregular heartbeat, especially if you are feeling stressed. These can be signs of a condition known as stress cardiomyopathy.

The following side effects have also been reported:

Not known: Frequency cannot be estimated from the available data

Reporting of side effects:

- 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.

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 HPRA Pharmacovigilance,

Earlsfort Terrace,

IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website:www.hpra.ie;

email:medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ADRENALINE 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 ampoule in the outer carton in order to protect from light.

For single use only. If only part of an ampoule is used, the remaining solution should be discarded.

The solution should not be used if it is discoloured in any way.

This medicine should not be mixed with any other drugs.

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 (Epinephrine) as Adrenaline (Epinephrine) Acid Tartrate. Each 1ml of this solution for injection contains Adrenaline (Epinephrine) Acid Tartrate equivalent to 1mg Adrenaline (Epinephrine) as the active ingredient.

The other ingredients are sodium metabisulphite (E223), sodium chloride and sodium hydroxide or hydrochloric acid in water for injections.

What Adrenaline Injection looks like and contents of the pack

Adrenaline Injection is a clear colourless, sterile solution for injection. Each 1ml glass ampoule contains Adrenaline (Epinephrine) acid Tartrate equivalent to 1mg Adrenaline (Epinephrine).

Pack size: 10 ampoules packaged together in cartons.

Marketing Authorisation Holder

Mercury Pharmaceuticals (Ireland) Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

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