PACKAGE LEAFLET: INFORMATION FOR THE USER

# Adrenaline (Epinephrine) 1:10,000 Injection

Adrenaline acid tartrate

**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, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist . This includes any possible side effects not listed in this leaflet. See section 4.

This medicine will be referred to as Adrenaline Injection in the rest of this leaflet

**What is in this leaflet**


1. What Adrenaline Injection is and what it is used for.
2. What you need to know before you use Adrenaline Injection.
3. How Adrenaline Injection is given.
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 (Epinephrine) belongs to a group of medicines used for the treatment of serious shock produced by a severe allergic reaction or collapse. It may also be used to restart your heart if it has stopped.

## 2. What you need to know before you use Adrenaline Injection

**You should not be given Adrenaline Injection if you are:**
- allergic to adrenaline or any of the other ingredients of this medicine listed in section 6
- have severe heart disease particularly if it is associated with an increased heart rate
- are suffering from any infection, disease or tumour of the brain
- have atherosclerosis which is a narrowing, and hardening of the body's blood vessels (your doctor will advise you).
- are in shock (other than that caused by a sudden life threatening reaction).
- are suffering from glaucoma (increased pressure in the eye).
- are having or are about to have an operation under general anaesthetic.
- are in labour

**Warnings and precautions**

Talk to your doctor or pharmacist before being 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 a condition called congenital long QT syndrome or problems with heart rhythm
- 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.
- you are taking Monoamine oxidase (MAO) inhibitors

**Other medicines and Adrenaline Injection**

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

Medicines that may interact with Adrenaline Injection include:
- drugs to treat high blood pressure, heart conditions, depression or thyroid problems.
- insulin or oral hypoglycaemics (drugs used to treat diabetes).
- volatile halogen anaesthetics (gas used during anaesthesia)
- certain antidepressants e.g. Imipramine
- any cough or cold remedies (sympathomimetics)

**Pregnancy, breast-feeding and fertility**

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

**Driving and using machines**

Having Adrenaline injection does not affect your ability to drive or use machines.

**Adrenaline Injection contains Sodium Metabisulfite**

The product also contains Sodium Metabisulfite which may cause allergic type reactions in some people, which can lead to breathing difficulties or collapse. People with a history of asthma or allergies (hypersensitivity) are most likely to experience these problems.
This medicinal product contains 2.695 mg of sodium per ml of solution for injection: to be taken into consideration by patients on strict sodium diet.

## 3. How Adrenaline Injection is given

Your doctor, nurse or paramedic will give Adrenaline Injection to you into a vein (intravenous) or into a bone (intraosseous). Your doctor will decide the correct amount for you and when and how this should be given.

**To restart your heart**

**Adults and Children over 12 years**

The recommended dose is 10ml by injection into a vein (intravenously).

If your doctor cannot give you an injection into a vein then the medicine can be given into a bone.

**Children under 12 years**

Not recommended.

**The elderly**

Your doctor will give Adrenaline Injection to you with caution.

**To treat life threatening allergic reactions (acute anaphylaxis)**

Adrenaline injection may only be given by a doctor experienced in using Adrenaline to treat life threatening allergic reactions.

**Adults**

Adults will be given a dose of 50 micrograms (0.5ml of Adrenaline Injection) repeated as necessary until the desired response is achieved.

**Children**

The exact dose of Adrenaline injection will be determined by your doctor. A child may only need to be given a dose as low as 1 microgram per kilogram of bodyweight.

**If you take more of Adrenaline Injection than you should**

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

However, the symptoms of overdose include:
- cardiac dysrhythmia (irregular heartbeats/cardiac arrest),
- hypertension (with risk of cerebral haemorrhage),
- vasoconstriction (narrowing of the blood vessels for example cutaneous, in the extremities or kidneys),
- acute angina attacks,
- risk of heart attack.

*Continued overleaf*

## 4. Possible side effects

Like all medicines Adrenaline Injection 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).

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
- weakness or sweating
- changes in the rhythm and speed of the heart
- high blood pressure
- coldness of the arms or legs
- pallor (pale skin)
- 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
- bleeding in the head
- paralysis of one half of the body
- increased sugar levels in the blood
- breakdown of fat in the body.
- hyperglycaemia (high blood sugar levels)
- hypokalaemia (low potassium levels in the blood)
- mydriasis (dilation of the pupil)
- fainting

**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 Adrenaline Injection

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

Your doctor, nurse or paramedic will check that the expiry date on the label has not been passed before giving Adrenaline Injection to you. The expiry date refers to the last day of the month.

Adrenaline is sensitive to light; therefore the Adrenaline Injection must always be kept in the original outer carton.

Do not store above 25ºC and do not freeze.

You should not be given Adrenaline Injection if you notice it has been used or shows signs of visible damage.

## 6. Contents of the pack and other information

**What Adrenaline Injection contains**

The active ingredient is Adrenaline (as acid tartrate) 0.1mg per ml. The other ingredients are Sodium Chloride, Sodium Metabisulfite, Sodium Citrate, Citric Acid and Water for Injections. Dilute Hydrochloric acid may be added to adjust the acidity.

**What Adrenaline Injection looks like and contents of the pack**

Adrenaline Injection is a clear, colourless solution supplied in 1ml, 5ml and 10ml clear glass ampoules. Each pack contains 10 ampoules.


**Marketing Authorisation Holder:**
Martindale Pharma
Bampton Road,
Harold Hill,
Romford,
Essex,
RM3 8UG

**Manufacturer:**
Martindale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom.

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