PACKAGE LEAFLET: INFORMATION FOR THE USER D06684

Adrenaline (Epinephrine) Injection 1:10,000
(Referred to as 'Adrenaline injection' in this leaflet)

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, please ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

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What is in this leaflet:

1. What Adrenaline injection is, and what it is used for
2. What you need to know before Adrenaline injection is given
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 injection belongs to a group of medicines called adrenergic and dopaminergic agents.

This medicine is used for:
- Treatment of cardiac arrest (unexpected loss of heart function, breathing and consciousness),
- Treatment of acute anaphylaxis in adults (serious shock or collapse produced by a severe allergic reaction).

2. What you need to know before you are given Adrenaline Injection

You must not be given Adrenaline Injection:
If you are allergic (hypersensitive) to any ingredients of this medicine (listed in section 6) where an alternative presentation of Adrenaline or alternative vasopressor is available.

Warnings and precautions
Adrenaline injection is indicated for emergency treatment. Continuous medical supervision is necessary after administration.

The prefilled syringes must be used with compatible needle-free connectors (NFCs).
Using an incompatible NFC may lead to blockages, potentially delaying the delivery of emergency medication.

To avoid such issues, ensure compatible NFCs are procured in advance and stored together with the Aurum range of prefilled syringes. List of compatible NFCs can be found in the link below:
https://ethypharm.co.uk/files/aurum-connector-compatibility-chart.pdf

Precautions for use
The risk of side effects is increased if you:
- have medical history of hyperthyroidism (disease of the thyroid gland),
- have severe renal insufficiency,
- suffer from hypercalcaemia (increase of calcium concentration in the blood),
- suffer from hypokalaemia (decrease of potassium concentration in the blood),
- have diabetes mellitus,
- have cardiac disease or arterial hypertension,
- have brain damage or hardening of the arteries in the brain,
- have glaucoma (increased pressure in the eye),
- have prostate disorders,
- are elderly,
- are pregnant.

Tell your doctor if you have a condition called congenital long QT syndrome or problems with heart rhythm.

Other medicines and Adrenaline injection
Tell your doctor if you are taking, have recently taken or might take any other medicines.
Medicines that may interact with Adrenaline injection include:
- Volatile halogen anaesthetics (gas used during anaesthesia),
- Certain antidepressants,
- Drugs to treat high blood pressure, heart conditions,
- Drugs to treat diabetes.

Pregnancy & breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you are given this medicine.

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

Adrenaline injection contains sodium This medicinal product contains 2.70 mg of sodium per ml of solution for injection. This needs to be taken into consideration by patients on strict sodium diet.

The product also contains Sodium Metabisulphite which may cause allergic (hypersensitive) type reactions in some people and can lead to breathing difficulties or collapse. People with a history of asthma or allergies are most likely to experience these problems.

3. How Adrenaline injection is given

Your doctor, nurse or paramedic will give Adrenaline injection to you either 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.

Adrenaline must not be injected into the fingers, toes, ears, nose or genital area.

This medicinal product is not intended to deliver volumes of less than 2ml.
In case of life threatening allergic reactions (acute anaphylaxis):

Adults will be given a dose of 0.05 mg (0.5 ml of Adrenaline 1:10,000 solution) repeated as necessary until the desired response is achieved.

In case of cardiac arrest:
Adults: 1 mg (10 ml of Adrenaline 1:10,000 solution) is given into a vein or into a bone every 3-5 minutes until the heart starts to work.

Children above 5 kg: 10 micrograms/kg (0.1 ml/kg of Adrenaline 1:10,000 solution) is given into a vein or into a bone every 3-5 minutes until the heart starts to work.

This medicinal product is not suitable for delivering a dose of less than 0,5 ml and should therefore, not be used in neonates and infants for which the body weight is less than 5 kg.

4. Possible side effects

Like all medicines, Adrenaline injection can cause side effects, although not everybody gets them.
- anxiety
- difficulty in breathing
- nervousness
- fear
- sweating
- palpitations (irregular or faster heart beat)
- tachycardia (increased heart rate)
- pallor (unhealthy pale appearance)
- tremors (shaking)
- weakness
- dizziness
- headache
- feeling sick (nausea)
- being sick (vomiting)
- coldness of the fingers and toes
- hallucinations
- syncopes (fainting)
- high blood sugar levels (hyperglycaemia)
- low potassium levels in the blood (hypokalaemia)
- increased acidity in the blood (metabolic acidosis)
- dilatation of the pupil (mydriasis)

In high dosages or for patients sensitive to adrenaline, **side effects are:**
- irregular heartbeats/cardiac arrest (cardiac dysrhythmia),
- 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 acute myocardial infarction.

Repeated local injections may produce necrosis (tissue damage) at the site of injection as a result of vascular constriction (blood vessel constriction).

In all cases, after administration of Adrenaline injection medical supervision is necessary.

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 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 out of the sight and reach of children.

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

Adrenaline (Epinephrine) is sensitive to light, therefore Adrenaline injections must always be kept in the original outer carton.

Do not store above 25°C and do not freeze.

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

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. Content of the pack and other information

What Adrenaline (Epinephrine) Injection 1:10,000 contains

The active ingredient is Adrenaline (Epinephrine) as acid tartrate.

Each 10ml solution for injection contains 1mg of adrenaline(epinephrine) as the acid tartrate.

The other ingredients are Sodium Chloride, Citric Acid Monohydrate, Sodium Citrate Dihydrate, Sodium Metabisulphite 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 a pre-filled syringe. Each prefilled syringe contains 10ml of the solution.

Marketing Authorisation Holder:
Aurum Pharmaceuticals Ltd.
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The following information is intended for healthcare professionals only:
Intravenous adrenaline should only be administered by those experienced in the use and titration of vasopressors in their normal clinical practice.

Cardiopulmonary resuscitation:
10 ml of the 1:10,000 solution (1 mg) by the intravenous or intraosseous route, repeated every 3-5 minutes until return of spontaneous circulation.
Endotracheal use should only be considered as a last resort if no other route of administration is accessible, at a dose of 20 to 25 ml of the 1:10,000 solution (2 to 2.5 mg).

In cardiac arrest following cardiac surgery, Adrenaline should be administered intravenously in doses of 0.5 ml or 1 ml of 1:10,000 solution (50 or 100 micrograms) very cautiously and titrated to effect.

Acute anaphylaxis
Titrate using intravenous boluses of 0.5 ml 1:10,000 solution (0.05 mg) according to response.
Adrenaline 1 mg/10 ml (1:10,000) solution for injection in pre-filled syringe is not recommended for intramuscular use in acute anaphylaxis. For intramuscular administration, a 1 mg/ml (1:1000) solution should be used.

Paediatric Population:
This medicinal product is not appropriate to deliver a dose of less than 0.5 ml and should therefore not be used by the intravenous or intraosseous route, in neonates and infants with body weight less than 5 kg.

Cardiac arrest in children:
Intravenous or intraosseous route (above 5 kg only): 0.1 ml/kg of 1:10,000 solution (10 micrograms/kg) to a maximum single dose of 10 ml of 1:10,000 solution (1 mg), repeated every 3-5 minutes until return of spontaneous circulation.

Endotracheal use (any body weight) should only be considered as a last resort if no other route of administration is accessible, at a dose of 1 ml/kg of 1:10,000 solution (100 micrograms/kg) to a maximum of single dose of 25 ml of 1:10,000 solution (2.5 mg).

Strictly respect the protocol below:
The pre-filled syringe is for single patient use only. Discard the syringe after use. **Do not reuse.**

The product should be inspected visually for particles and discolouration prior to administration. Only clear colourless solution free from particles or precipitates should be used.

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