PACKAGE LEAFLET: INFORMATION FOR THE USER

Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection

(adrenaline)

Because of your condition it may not be possible for you to read this leaflet before you are given Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection.
- The leaflet will be kept for you as you may wish to read it later.
- If you have further questions, please ask your doctor or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection (hereafter 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 (Epinephrine) belongs to a class of drugs called sympathomimetic agents.
Adrenaline injection can be used for the emergency treatment of severe allergic reactions.

2. What you need to know before Adrenaline Injection is Given

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)
- Adrenaline injection should not be used in areas such as fingers, toes, ears, nose, genitalia or buttocks, as the blood supply to these areas might become inadequate.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before using 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 have atherosclerosis which is a narrowing and hardening of the body's blood vessels (your doctor will advise you).

If any of the above apply to you or your child please tell your doctor before you are given this medicine.

Other medicines and Adrenaline Injection
Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 such as imipramine, amitriptyline, 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") such as hydrochlorothiazide, furosemide
- 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 labour 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 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 Adrenaline Injection.

Adrenaline Injection contains sodium metabisulphite
This medicine contains Sodium Metabisulphite which may cause allergic (hypersensitive) 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.

3.How Adrenaline Injection is given

Your doctor will give Adrenaline Injection to you into a muscle (Intramuscular - IM), however, in emergencies your doctor may give you a diluted injection into your vein (intravenous - IV).
Adrenaline injection must NOT be given in areas such as fingers, toes, ears, nose, genitalia or buttocks , as the blood supply to these areas might become inadequate.
If repeated injections are required your doctor will change the site of injection.
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.

Adults

The usual dose is 0.5ml. If necessary, this dose may be repeated several times at 5-minute intervals.

Elderly
There are no specific dose regimens for adrenaline injection in elderly patients, however adrenaline should be used with great caution.

Children
The following doses of Adrenaline Solution for Injection

Age	Dose
Over 12 years	0.5 mg IM (0.5ml 1mg/ml solution) 0.3 mg IM (0.3ml 1mg/ml solution) if the child is small or pre-pubertal)
6 - 12 years	0.3 mg IM (0.3ml 1mg/ml solution)
6 months - 6 years	0.15 mg IM (0.15ml 1mg/ml solution)
Under 6 months	0.01mg/kg IM (0.01ml/kg 1mg/ml solution)

are recommended:
If necessary, these doses may be repeated several times at 5 - 15 minutes intervals according to blood pressure, pulse and respiratory function.

A small volume syringe should be used.

If you think you have been given more Adrenaline Injection more than you should.
As this medicine will be given to you whilst you are in

The following information is for healthcare professionals only:

Preparation and handling
Do not use Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection if you notice that it is discoloured.
Repeated local administration may cause necrosis at the injection site.

The best site for intramuscular injection is anterolateral in the middle third of the thigh. Needle used for the injection must be long enough to ensure that the adrenaline reaches the muscle.
Intramuscular injection in fingers, toes, ears, nose genitalia or buttocks should be avoided due to the risk of tissue necrosis.

Prolonged administration may cause metabolic acidosis, renal necrosis or tachyphylaxis.

Use of adrenaline injection should be avoided or done with the greatest caution in patients under general anesthesia with halothane or other halogenated anesthetics, due to the risk of developing ventricular fibrillation.

Do not mix with other medicines unless compatibility has been confirmed.
Adrenaline injection should not be used during the second stage of labour.

Accidental intravascular injection may result in cerebral hemorrhage due to the sudden blood pressure rise.
Begin monitoring the patient as soon as possible (heart rate, blood pressure, ECG, pulse oximetry) to assess the response to adrenaline.

Incompatibilities
Adrenaline/epinephrine is rapidly denatured by oxidising agents and alkalis including sodium bicarbonate, halogens, nitrates, nitrites, and salts of iron, copper and zinc.

Dosage and method of administration
Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection is intended for intramuscular use.

Do not give Adrenaline (Epinephrine) 1 mg/ml (1:1000) Solution for Injection intravenously.

Intravenous administration of adrenaline for anaphylaxis requires the use of a 0.1mg/ml (1:10000) adrenaline solution.
The IM route is generally preferred in the initial treatment of anaphylaxis, the IV route is generally more appropriate in the Intensive Care Unit or Emergency Department setting. Adrenaline (Epinephrine) 1mg/ml (1:1000) solution for injection is not suitable for IV use.
If the adrenaline 0.1 mg/ml (1:10000) injection is not available, Adrenaline (Epinephrine) 1mg/ml (1:1000) solution must be diluted to 0.1 mg/mL (1:10000) before IV use. The IV route for injection of adrenaline must be used with extreme caution and is best reserved for specialists familiar with IV use of adrenaline.

Acute anaphylaxis
Intramuscular route of administration is preferred for most individuals in need of treatment adrenaline to acute anaphylaxis.

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For adults, the usual dose is 0.5 mg (0.5ml of Adrenaline 1mg/ml (1:1000)). If necessary, this dose may be repeated several times at 5-minute intervals according to blood pressure, pulse and respiratory function.

Elderly:
There are no specific dosage regimes for adrenaline injection in elderly patients. However, Adrenaline should be used with great caution in these patients who may be more susceptible to the cardiovascular side effects of adrenaline.

Paediatric population
The following doses of Adrenaline (Epinephrine) 1mg/ml (1:1000) Injection are recommended:

Age Dose
Over 12 years 0.5 mg IM (0.5ml 1mg/ml (1:1000) solution)
0.3 mg IM (0.3ml 1mg/ml (1:1000) solution) if the child is small or pre-pubertal)

6 - 12 years 0.3 mg IM (0.3ml 1mg/ml (1:1000) solution)

6 months - 6 years 0.15 mg IM (0.15ml 1mg/ml (1:1000) solution)

Under 6 months 0.01mg/kg IM (0.01ml/kg 1mg/ml (1:1000) solution)

If necessary, these doses may be repeated several times at 5 - 15 minutes intervals according to blood pressure, pulse and respiratory function.
A small volume syringe should be used.

Disposing
Non-used drugs and waste should be disposed of in accordance with local requirements.

Overdose

Sign
Adrenaline overdose leads to severe hypertension. Cerebral, cardiac or vascular accidents which could be potentially fatal may occur as a result (cerebral haemorrhage, dysrhythmias such as transient bradycardia followed by tachycardia that may result in arrhythmia, myocardial necrosis, acute pulmonary oedema, renal insufficiency).

Treatment
The effects of adrenaline may be counteracted, depending on the condition of the patient, by administration of quick-acting vasodilators, of quick-acting alpha-adrenoreceptor blocking agents (e.g. phentolamine), or beta-adrenoreceptor blocking agents (e.g. propranolol). However, due to the short half-life of adrenaline, treatment with these medicines may not be necessary. In case of prolonged hypotensive reaction, administration of another vasopressive agent such as noradrenaline may be required.

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.

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 using 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
- a dry mouth or producing too much saliva
- weakness or sweating
- changes in the rhythm and speed of the heart
- palpitation (fast or irregular heartbeat), tachycardia (abnormally fast resting heart rate), angina (chest pain with varying intensity)
- 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
- bleeding in the head
- paralysis of one half of the body
- increased sugar levels in the blood
- breakdown of fat in the body
- decreased blood potassium levels
- pulmonary oedema
- chest pain (acute angina)
- heart attack (acute myocardial infarction)
- Pale appearance (Pallor)
- Passing out (syncope)
- dilation of the pupil (mydriasis)

In patients with Parkinson's disease Adrenaline (Epinephrine) may increase rigidity (stiffness) and tremors (shaking).

After being given this product, you may experience slight pain, minor bruising/bleeding or some left over liquid in the place where you have been injected

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 the Yellow Card Scheme at: 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 all medicines 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 administering Adrenaline Injection to you. The expiry date refers to the last day of the month.
You should not be given the Adrenaline Injection if you notice 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. Contents of the Pack and Other Information

What Adrenaline Injection contains
The active ingredient is Adrenaline (Epinephrine) (as acid tartrate) 1mg per ml.
This medicinal product contains less than 1mmol sodium (23mg) per dose as Sodium Chloride (essentially 'sodium-free').
The other ingredients are Sodium Metabisulphite and Water for Injections.
Hydrochloric acid and sodium hydroxide may be added to adjust the acidity.

What Adrenaline Injection looks like and contents of the pack
The Adrenaline Injection is a clear, colourless solution supplied in a pack of 10 glass ampoules each containing 0.5, 1, 2, 5 or 10ml.

Marketing Authorisation Holder and Manufacturer:
Macarthys Laboratories Limited
Bampton Road,
Harold Hill,
Romford,
Essex,
RM3 8UG

This medicinal product is authorised in the Member States of the EEA under the following names:

UK	Adrenaline (Epinephrine) 1 mg/ml (1:1000) solution for Injection
FR	Adrenaline Ethypharm 1 mg/ml (1:1000) solution for injection
ES	Adrenalina Ethypharm 1 mg/ml (1:1000) solución inyectable
FI	Adrenalin Ethypharm
DE	Adrenaline Ethypharm 1 mg/ml (1:1000) solution for injection
DK	Adrenalin Ethypharm 1 mg/ml (1:1000) solution for injection
IT	Adrenalina Ethypharm
NO	Adrenalin Ethypharm
SE	Adrenalin Ethypharm 1 mg/ml (1:1000) solution for injection

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