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

What is Adrenaline Injection and what it is used for

Adrenaline (Epinephrine) belongs to a class of drugs called sympathomimetic agents. Adrenaline can be used for the emergency treatment of severe allergic reactions.

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

1. allergic to adrenaline, or to any of the other ingredients of this medicine (listed in section 6)
2. 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 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 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)

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 (hypersensitivity) 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.

Intramuscular 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 are recommended:

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 12 years</td>
<td>0.5 mg IM (0.5ml 1mg/ml solution)</td>
</tr>
<tr>
<td></td>
<td>0.3 mg IM (0.3ml 1mg/ml solution)</td>
</tr>
<tr>
<td>6 - 12 years</td>
<td>0.3 mg IM (0.3ml 1mg/ml solution)</td>
</tr>
<tr>
<td>6 months - 6 years</td>
<td>0.15 mg IM (0.15ml 1mg/ml solution)</td>
</tr>
<tr>
<td>Under 6 months</td>
<td>0.1mg/kg IM (0.01mg/kg 1mg/ml solution)</td>
</tr>
</tbody>
</table>

If repeated injections are required your doctor will use a smaller dose. If repeated injections are required your doctor will use a smaller dose.

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 of administration of adrenaline must be used with extreme caution and is best reserved for specialists familiar with the use of adrenaline.

4. Possible side effects

People who have a previous history of anaphylaxis may be more sensitive to adrenaline injection.

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too little of the medicine.

The following information is for healthcare professionals only:

Prevention 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 anaesthesia with halothane or other halogenated anaesthetics, 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 intravenous injection may result in cerebral ischaemia due to the sudden blood pressure rise.

Begin monitoring the patient as soon as possible for any heart rate, blood pressure, ECG, pulse oximetry to assess the response to adrenaline.

Adrenaline

Adrenaline (Epinephrine) is rapidly denatured by acidifying agents and alkalis including sodium bicarbonate, hydrochloric acid, nitrates, nitrates, and salts of iron, copper and zinc.

Dosing 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 prolonged use may be necessary, however it is unsuitable due to the risk of renal necrosis or tachyphylaxis.

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 of administration of adrenaline must be used with extreme caution and is best reserved for specialists familiar with the use of adrenaline.

Acute anaphylaxis

Intramuscular route of administration is preferred for most individuals in need of treatment adrenaline to acute anaphylaxis.
noradrenaline may be required. In case of prolonged hypotensive reaction, adrenaline, treatment with these medicines may not be necessary. 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:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 6 months</td>
<td>0.01mg/kg IM (0.01ml/kg 1mg/ml (1:1000) solution)</td>
</tr>
<tr>
<td>6 months - 6 years</td>
<td>0.15mg IM (0.15ml 1mg/ml (1:1000) solution)</td>
</tr>
<tr>
<td>6 - 12 years</td>
<td>0.3mg IM (0.3ml 1mg/ml (1:1000) solution)</td>
</tr>
<tr>
<td>Over 12 years</td>
<td>0.5mg IM (0.5ml 1mg/ml (1:1000) solution)</td>
</tr>
</tbody>
</table>

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

Choosing

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

Storage

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-adrenergic receptor blocking agents (e.g. phentolamine), or beta-adrenergic receptor 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 vasoactive agent such as noradrenaline may be required.

or too much, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

As all medicines Adrenaline Injection can cause side effects, although not everybody gets them. If you experience any of these side effects, stop using this medicine and report it 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
- abdominal disorder 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
- abnormal fast resting heart rate, angina (chest pain with varying intensity)
- high blood pressure
- coldness of the arms or legs
- breathlessness
- increased 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
- breakdown of muscle
- increased blood potassium levels
- prolonged oedema
- chest pain (acute angina)
- heart attack (acute myocardial infection)
- Palpitations (Palpitating)
- Passing out (syncope)
- Dilatation 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 light pain, minor bruising/bleeding or some left over liquid in the place where you have been injected.

Reporting of side effects

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 for injection. Hydrochloric acid and sodium hydroxide may be added to adjust the acidity.

Marketing Authorisation Holder and Manufacturer:

Macartys Laboratories Limited
Bampton Road,
Romford,
Essex,
RM16 6DS

The Adrenaline Injection is supplied in a pack of 10 glass ampoules each containing 0.5, 1, 2, 5 or 10ml.

Product licence number: PL 01883/6118R

This leaflet was last revised in: 09/2019