Package leaflet: Information for the user

Adrenalin Martindale Pharma 0,1 mg solution for injection
adrenaline

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.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Adrenalin Martindale Pharma is and what it is used for

Adrenalin Martindale Pharma is used in cardiopulmonary resuscitation and the treatment of sudden life-threatening allergic reactions (acute anaphylaxis).

2. What you need to know before you are given Adrenalin Martindale Pharma

Do not use Adrenalin Martindale Pharma:
- if you are allergic to adrenaline, sodium metabisulphite (a preservative) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Adrenalin Martindale Pharma

Because of the increased risk of adverse reactions, adrenaline should be used with caution in patients with
- Cardiovascular disease (such as angina pectoris, heart muscle disease, heart rhythm abnormalities, pulmonary heart disease, atherosclerosis and high blood pressure)
- Overactive thyroid
- Adrenal gland tumour
- Narrow-angle glaucoma (glaucoma - increased pressure in the eye)
- Severely impaired kidney function
- Enlarged prostate which causes the urine remaining in the bladder
- Increased amount of calcium in the blood
- Decreased amount of potassium in the blood
- Diabetes.

Should be used with caution in elderly and pregnant patients.

Other medicines and Adrenalin Martindale Pharma
Tell your doctor, pharmacist or nurse if you are using or have recently used any other medicines.

This is especially important if you take any of the following:
- Beta blocking medicines (e.g. pindolol and propranolol) since they can cause increased blood pressure and reduced heart rate.
- Medicines for general anaesthesia because concomitant use of certain medicines for general anaesthesia may increase the risk of heart rhythm disturbances
- Medicines that may increase the risk for heartbeat disturbances (e.g. digitalis and quinidine)
- Some antidepressants (e.g. protriptyline, maprotiline), since the effects of adrenaline may be increased.
- Insulin or diabetes medicines taken orally, since adrenaline increases the blood sugar level.

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, pharmacist or nurse for advice before you are given this medicine.

Experience in the treatment of pregnant women is limited..

Adrenaline passes overto breast milk. Breast-feeding should be avoided by mothers receiving adrenaline.

There are no animal studies with respect to effect on fertility.

Adrenalin Martindale Pharma contains sodium metabisulphite and sodium
Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains less than 1 mmol sodium (23 mg) per ml solution for injection, that is to say essentially ‘sodium- free’.

3. How you are given Adrenalin Martindale Pharma

Adrenalin Martindale Pharma is administrated to you by your doctor or nurse.

Dose and method of administration
The dose is determined by your doctor and individually adjusted for you.

Cardiac arrest (cardiopulmonary resuscitation)
Adults and children over 12 years: 1 mg intravenous bolus dose every 3-5 minutes.

Children below 12 years: 0.01 mg/kg intravenous bolus dose. Maximum single dose is 1 mg.

Infants: 0.01-0.03 mg/kg intravenous bolus dose.

Life-threatening allergic reactions
Intramuscular administration (i.e. injection into a muscle) of 1 mg/ml of adrenaline solution is recommended for the treatment of anaphylactic shock.

If you are given too much Adrenalin Martindale Pharma
It is unlikely that you will receive too much of this medicine as it is only adminstered to you by your doctor or nurse.
Overdose of adrenaline can cause agitation, anxiety, tremors, headaches, increased heart rate, palpitations, pallor, cold sweat, nausea, vomiting. Enlargement of the pupils, increased blood pressure, pulmonary edema, irregular heartbeat, heart failure can be seen at high doses.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most common side effects of adrenaline are effects on the circulation and central nervous system. Approximately one third of patients experience side effects.

Common side effects (may affect up to 1 in 10 people)
- Headache, dizziness
- Increased heart rate, increased blood pressure, heart rhythm disorders.
- Anxiety, tremor

Reporting of side effects
If you get any side effects, talk to your doctoror, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adrenalin Martindale Pharma

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

For single use only.

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 label and carton after EXP. The expiry date refers to the last day of that month.

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 Adrenalin Martindale Pharma contains
- The active substance is adrenaline. Each ml of solution contains 0.1 mg of adrenaline (as adrenaline tartrate)
- The other ingredients are sodium chloride, citric acid monohydrate, sodium citrate, sodium metabisulphite (E223), hydrochloric acid (pH adjustment) and water for injections.

What Adrenalin Martindale Pharma looks like and contents of the pack

Adrenalin Martindale Pharma is a clear and colourless solution.
Pack size: 10 x 10 ml glass ampoules (type I).

Marketing Authorisation Holder and Manufacturer
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92213 Saint-Cloud Cedex
France
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

<To be completed nationally>

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The following information is intended for healthcare professionals only:

Cardiopulmonary resuscitation:
Adrenaline should be dosed and administered according to current treatment recommendations. The following posology of adrenaline is based on the recommendations of the ERC (European Resuscitation Council) in 2015.

Adults and children over 12 years
1 mg using intravenous boluses every 3-5 minutes.
If the drug is injected via a peripheral vein catheter, the drug must be flushed out with at least 20 mL of 0.9% sodium chloride for injection (to facilitate entry into the central circulation).
If venous access is not available, intraosseous administration is recommended

Children below 12 years
0.01 mg/kg using intravenous boluses. Maximum single dose is 1 mg.

Infants
0.01-0.03 mg/kg using intravenous boluses. Administration via an umbilical vein catheter is recommended.

Acute anaphylaxis
Always check that the correct strength of adrenaline solution is used in the treatment of anaphylaxis. The equipment for the treatment of anaphylactic shock must be very clearly distinguished between 0.1 mg/ml and 1 mg/ml of adrenaline solution.
Intramuscular administration of 1 mg/ ml adrenaline solution is preferred for the treatment of anaphylactic shock. It is also important that time is not wasted in attempting to find intravenous line if the intramuscular injection may still be possible.

In the treatment of anaphylaxis, adrenaline for intravenous administration should only be administered by experienced personnel under the observation of heart rate and blood pressure. The 0.1 mg/ml solution of adrenaline is given to adults as 0.05 mg iv bolus dose and titrated in increments of boluses of 0.05 mg according to response.

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

Adrenaline may be mixed with 0.9% sodium chloride for injection, but is incompatible with 5% sodium chloride for injection. The stability of adrenaline in 5% dextrose injection decreases when the pH exceeds 5.5.