

PACKAGE LEAFLET: Information for the user

ADRENALINE

Solution for injection – 1 mg / ml (0.1%)

(Adrenaline hydrogentartrate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What Adrenaline is and what it is used for
2. Before you take Adrenaline
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1. WHAT ADRENALINE IS AND WHAT IT IS USED FOR

Adrenaline is an endogenous substance that is produced in the adrenal medulla and has important physiological effects. It is a potent agonist at both alpha and beta adrenoceptors, although the effect on beta adrenoceptors is more marked, particularly at lower doses.

The major effects of adrenaline are dose-related and include:

dilatation of the bronchi, narrowing of blood vessels, increased heart rate and contractility (positive chronotropic and inotropic effect) and stimulation at central level. Adrenaline is a histamine antagonist. It is used for the treatment of life emergencies.

Adrenaline is used in acute allergic reactions and anaphylactic shock.

It is also used in advanced cardiac life support.

Your doctor may have given Adrenaline for another purpose. Ask your doctor if you want to know why you have been given this drug.

2. BEFORE YOU TAKE ADRENALINE

Do not take Adrenaline if you:

- are allergic to adrenaline or to any other ingredient of the solution;
- suffer from cerebral atherosclerosis or organic brain damages;
- suffer from cardiomyopathia, coronary insufficiency, hypertension;
- suffer from narrow angle glaucoma;
- suffer from diabetes;
- suffer from phaeochromocytoma and hyperthyroidism;
- will undergo total anesthesia with halogenated hydrocarbons or cyclopropane;
- are pregnant;
- have circulatory collapse because of phenothiazines;
- are taking monoamine-oxidase inhibitors (MAO-I);
- have had anaphylactic shock during total anesthesia with halogenated hydrocarbons or cyclopropane.

Adrenaline is contraindicated to be administered in extremities (fingers, toes, nose, genitals, etc.).

If you think that any of the above conditions applies to you, talk first to your doctor before using this drug and follow his instructions.

Take special care with Adrenaline

- Adrenaline should be used with caution in patients with cardiovascular disorders, since they may have an increased susceptibility to its effects. Particular care is needed in patients with cardiac arrhythmias, ischaemic heart disease, or hypertension.

- Take special care if you have or have ever had any health disorder, particularly the following:
- Cardiovascular disorders, pulmonar oedema, hypertension, hyperthyroidism, diabetes, psychoneurotic disease, asthma, cerebral hemorrhage.
- Adrenaline should be used with extreme caution in elderly and children.
- Adrenaline should not be used with other drugs because they may affect its effect.
- This drug contains sodium metabisulphite, which may cause allergic reactions (including anaphylactic shock) in sensitive people. The most sensitive people to sulphites are asthmatic patients.

Taking other medicines

Interactions with adrenaline are complex and may be hazardous.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This is especially important for the following medicines:

- volatile anaesthetics, particularly cyclopropane or halothane because hazardous arrhythmias may occur;
- levothyroxine (thyroid synthetic hormone) or antihistamines, because they may potentiate the effect of adrenaline;
- drugs that affect cardiac conduction, such as cardiac glycosides and antiarrhythmics;
- MAO inhibitors (MAO – I), because they may potentiate the effects of adrenaline;
- tricyclic antidepressants, because they block the inactivation of adrenaline by uptake into the nerve endings and may increase its effect by causing hypertension and arrhythmia;
- direct-acting vasodilators or alpha-blockers, because these drugs may neutralise the hypertensive effect of adrenaline;
- beta-blockers, mainly nonselective ones, because concomitant administration with adrenaline may result in severe hypertension;
- clonidine, because there is a risk of hypertension;
- entacapone, because may potentiate the effect of adrenaline;
- dopexamine, because may potentiate the effect of adrenaline;
- ergotamine and methysergide;
- oxytocine.

Pregnancy

Category C.

Adrenaline crosses placenta.

Inform your doctor or pharmacist if you are pregnant or think you may be pregnant.

Adrenaline is contraindicated during pregnancy because it may restrict blood supply to placenta, cause tachycardia, cardiac irregularities, extrasystoles in fetus and can delay the second phase of birth.

Breastfeeding

Adrenaline is distributed into breast milk.

Inform your doctor or pharmacist if you are breastfeeding!

Your doctor or pharmacist will discuss on its benefits and risks during breastfeeding.

Driving and using machines

Be careful if you are driving or using machines.

Important information about some of the ingredients of Adrenaline

This drug contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE ADRENALINE

Adrenaline is a potentially dangerous drug used to treat conditions where life is threatened and should be used with medical advice.

Its administration must be done only by specialized personnel.

It is very important to emphasize that adrenaline is usually given by intramuscular injection, although it may also be given subcutaneously.

In extreme emergencies, where a more rapid effect is required, adrenaline may be given as a **dilute solution** (1:10 000 or 1:100 000) by very slow intravenous injection or by slow intravenous infusion. This may be into a central or peripheral vein, but in the latter case it should be accompanied by at least 20 mL of intravenous fluid.

In anaphylactic shock: the usual dose is 0.5 mg (0.5 ml of the solution diluted 1:1 000 (0.1%)) by intramuscular injection repeated as necessary every 5 minutes.

The dose for children depends on age and weight, but it is usually about 0.01 mg/kg by intramuscular injection.

In cardiac arrest: the adults dose is 1 mg intravenously (10 ml of the solution diluted 1:10 000), which may be repeated every 2 to 3 minutes throughout the resuscitation procedure.

The dose for children is 0.01 mg/kg intravenously.

Intravenous administration should be done as a diluted solution (1:10 000) and slowly.

In status asthmaticus: if adrenaline is to be used, the adult dose is 0.3 – 0.5 mg (0.3 - 0.5 ml of the solution diluted 1:1 000) subcutaneously or intramuscularly.

The dose for children is 0.01 ml/kg (0.01 mg/kg).

If you feel that the effects of adrenaline are too strong or too weak, talk to your doctor or pharmacist.

If you take more Adrenaline 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.

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

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they can be serious, most of the times not. Do not panic from this list of possible side effects.

You may not get any of them.

Talk to your doctor if any of the following side effects bothers you:

Side effects are listed below according to their frequency:

Very common: can affect more than 1 in 10 patients.

Common: can affect 1 to 10 patients among 100.

Uncommon: can affect 1 to 10 patients among 1,000.

Rare: can affect 1 to 10 patients among 10,000.

Very rare: can affect less than 1 patient in 10,000.

Not known: frequency cannot be estimated from the available data.

Rare or very rare

- cardiomyopathy

Not known

- *cardiovascular*: cardiac arrhythmia, palpitations, severe hypertension (particularly in patients with hyperthyroidism or hypertension), angina pain in predisposed patients, cerebral and subarachnoidal hemorrhage;
- *in central nervous system*: anxiety, headache, restlessness, tremor, weakness, hemiplegia, dizziness and insomnia;
- nausea, vomiting, dyspnea, severe metabolic acidosis, hypokalemia, pallor, coldness of extremities, urticaria, sweating, hypersalivation, dry mouth, reduced appetite;
- blisters and bleeding at the injection site;
- necrosis at the injection site after repeated injections;
- transient increase of blood glucose levels;
- increased serum lactic acid.

In high doses, adrenaline may cause cardiac arrhythmias and a sharp rise in blood pressure (sometimes leading to cerebral haemorrhage and pulmonary oedema); these effects may occur at normal dosage in susceptible subjects.

Extravasation of parenterally administered adrenaline similarly causes intense vasoconstriction, resulting in tissue necrosis and sloughing.

If you get any other side effect not mentioned in this leaflet, please talk to your doctor or pharmacist.

5. HOW TO STORE ADRENALINE

Store the ampoules below 25°C.

Protect from light.

Keep in the original package and do not use after the expiry date which is stated on the packaging.

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

6. FURTHER INFORMATION

What Adrenaline contains

The active substance is adrenaline hydrogentartrate.

Each ampoule 1 ml contains 1 mg adrenaline (as hydrogentartrate).

The other ingredients are: sodium metabisulphite, sodium chloride, hydrochloric acid may be added for pH adjustment, water for injection.

Contents of the pack

Carton box with 10 ampoules of 1 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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