Package leaflet: Information for the user
Adrenaline 1:1000 (1mg/mL) Solution for injection
Adrenaline

Read all of this leaflet carefully before you are given 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

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1. What Adrenaline 1:1000 (1mg/mL) Solution for injection is and what it is used for

Adrenaline belongs to a class of medicinal products called adrenergic and dopaminergic agents. Adrenaline 1:1000 (1mg/mL) Solution for injection is used in life-threatening emergencies such as severe allergic reactions or cardiac arrest.

2. What you need to know before you are given Adrenaline 1:1000 (1mg/mL) Solution for injection

Do not use Adrenaline 1:1000 (1mg/mL) Solution for injection:
- if you are allergic to adrenaline or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before being given Adrenaline 1:1000 (1mg/mL) Solution for 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 tumor on the adrenal gland)
- you have low blood levels of potassium or high blood levels of calcium
- you have a tumor 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).

Speak to your doctor if any of these apply to you before you are given this medicine.

Other medicines and Adrenaline 1:1000 (1mg/mL) Solution for injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
A large number of medicinal products can interact with Adrenaline 1:1000 (1mg/mL) Solution for injection which can significantly alter their effects. These medicinal products include:
- monoamine oxidase inhibitors (MAOIs) such as moclobemide 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
- antidiabetic medicines like insuline or oral hypoglycaemic agents (e.g. glipizide)
- aminophylline and theophylline (medicines used to treat asthma)
- 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 labor 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 1:1000 (1mg/mL) Solution for 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 taking this medicine.
Adrenaline 1:1000 (1mg/mL) Solution for injection should not be used in pregnancy and during labour.
Adrenaline is distributed into breast milk. If you are breast feeding speak to your doctor before you are given Adrenaline 1:1000 (1mg/mL) Solution for injection.
Adrenaline should only be used during pregnancy and breast feeding if considered essential by your doctor.

Driving and using machines
This is unlikely to be applicable as you will not feel well enough to drive or use machinery.
Consult your doctor before considering such action.

Adrenaline 1:1000 (1mg/mL) Solution for injection contains sodium metabisulfite and sodium chloride
Sodium metabisulfite (a preservative) may rarely cause severe allergic (hypersensitivity) reactions and wheezing.
This medicinal product contains less than 1 mmol sodium (23 mg) per dose (essentially 'sodium free').
Adrenaline 1:1000 (1mg/mL) Solution for injection may be diluted in sodium chloride 0.9 %. This should be taken into consideration by patients on a controlled sodium diet.

3. How Adrenaline 1:1000 (1mg/mL) Solution for injection is given

Adrenaline may be injected into a muscle (intramuscularly) or into a bone (intraosseous). It must be diluted before injection into a vein. Adrenaline injection should not be used in areas such as fingers, toes, ears, nose or penis, as the blood supply to these areas might become inadequate.
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.

If you think you have been given more Adrenaline 1:1000 (1mg/mL) Solution for injection than you should
This is unlikely as your injection will be administered by a doctor or nurse.
Possible signs of overdosage include restlessness, confusion, pallor, abnormally fast resting heart rate (tachycardia), slow heart rate (bradycardia), irregular heart rate (cardiac arrhythmias) and cardiac arrest.
Talk to your doctor if you get any side effects so that he/she can give you appropriate treatment.
If you have already left the medical premises, contact your nearest hospital, doctor or pharmacist.
If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

The following side effects have also been reported (Unknown frequency):
- 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, damages may also occur in the extremities, kidneys and liver
- difficulty of not being able to pass water, urinary retention
- metabolic acidosis (an imbalance of certain constituents in your blood) may occur
- increase in tremors and rigidity in patients suffering from a condition called parkinsonian syndrome
- bleeding in the head

- paralysis of one half of the body
- increased sugar levels in the blood
- decreased blood potassium levels
- pulmonary oedema

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adrenaline 1:1000 (1mg/mL) Solution for injection

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 carton and ampoule label after EXP. The expiry date refers to the last day of that month. Store below 25 °C. Keep the ampoules in the outer carton in order to protect from light. For single use only. If only part of an ampoule is used, the remaining solution should be discarded.
Do not remove ampoule from the carton until ready to use. After diluting, the ready-to-use solution must be administered as soon as possible but should not, under any circumstances, be stored for longer than 24 hours at 2 to 8 °C, 3 hours at 23-27 °C when exposed to light, or 6 hours at 23 to 27 °C when protected from light.
Do not use this medicine if you notice discoloration, turbidity or precipitation. 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 1:1000 (1mg/mL) Solution for injection contains
- The active substance is adrenaline (epinephrine) as adrenaline (epinephrine) tartrate. Each 1 mL of this solution for injection contains 1 mg of adrenaline (epinephrine) as adrenaline tartrate.
- The other ingredients are sodium metabisulfite (E223), sodium chloride, water for injections, hydrochloric acid and sodium hydroxide.

What Adrenaline 1:1000 (1mg/mL) Solution for injection looks like and contents of the pack
Adrenaline 1:1000 (1mg/mL) Solution for injection is a clear colourless, sterile solution for injection, in an amber coloured type I glass ampoule.
Adrenaline 1:1000 (1mg/mL) Solution for injection is available in packs of 10, 25 and 50 ampoules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: BRADEX S.A. Pharmaceutical Products, 27 Asklipiou str., 14568 Krioneri, Attiki, Greece.
Manufacturer: DEMO S.A. Pharmaceutical Industry, 21st Km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece.

This medicinal product is authorised in the Member States of the EEA under the following names:
United Kingdom: Adrenaline 1:1000 (1mg/mL) Solution for injection
Germany: Adrenalin BRADEX 1mg/mL Injektionslösung
Spain: Adrenalina BRADEX 1 mg/mL Solución Inyectable
Hungary: Adrenalin BRADEX 1 mg/mL oldatos injekció

This leaflet was last revised in 05/2016.

If this leaflet is difficult to see or read please contact the following address for help: Athlone Laboratories, Ballymurray, Co. Roscommon, Ireland, Tel: +353-9066-61109, Email: medical@athlone-laboratories.com.

The following information is intended for healthcare professionals only:

Preparation and handling
Do not use this medicine if you notice discoloration.
Repeated local administration may produce necrosis at the sites of injection.
The best site for IM injection is the anterolateral aspect of the middle third of the thigh. The needle used for injection needs to be sufficiently long to ensure that the adrenaline is injected into muscle. Intramuscular injections of Adrenaline 1:1000 (1mg/mL) Solution for injection into the buttocks should be avoided because of the risk of tissue necrosis.
Prolonged administration may induce metabolic acidosis, renal necrosis and adrenaline-fastness or tachyphylaxis.
Adrenaline should be avoided or used with extreme caution in patients undergoing anaesthesia with halothane or other halogenated anaesthetics, in view of the risk of inducing ventricular fibrillation.
Adrenaline should not be used with local anaesthesia of peripheral structures including digits, ear lobe.
Do not mix with other agents unless compatibility is known.
Adrenaline should not be used during the second stage of labour.
Accidental intravascular injection may result in cerebral haemorrhage due to the sudden rise in blood pressure.
Monitor the patient as soon as possible (pulse, blood pressure, ECG, pulse oximetry) in order to assess the response to adrenaline.
Incompatibilities
Dilution
For intravenous administration, Adrenaline 1:1000 (1mg/mL) Solution for injection must be diluted to a 1 in 10,000 solution (a 1:10 dilution of the contents of the ampoule) with sodium chloride 0.9 %.
Posology and method of administration
Adrenaline 1:1000 (1mg/mL) Solution for injection is for intramuscular and intraosseous administration. For intravenous administration only after dilution.
Acute anaphylaxis
The **intramuscular (IM) route** is the route of choice for most individuals who have to be given adrenaline for the management of acute anaphylaxis, using the doses in table 1.
In general, the recommended dose of adrenaline is 0.01 mg per kilogram of body weight (10 micrograms/kg).
For adults, the usual recommended dose of adrenaline is 0.5 mg (500 micrograms).
For children, when the weight is not known, the table below, showing recommended doses according to age, can be advised:
Table 1. *Dose of IM injection of Adrenaline (Epinephrine) Injection BP 1 in 1000 for a severe anaphylactic reaction*

Age	Dose	Volume of adrenaline 1 in 1000 (1 mg/mL)
Adult	500 micrograms (0.5 mg)	0.5 mL
Child > 12 years	500 micrograms (0.5 mg)	0.5 mL
Child 6 – 12 years	300 micrograms (0.3 mg)	0.3 mL
Child 6 months - 6 years	150 micrograms (0.15 mg)	0.15 mL
Under 6 months	10 micrograms/kg (0.01 mg/kg)	0.01 mL/kg
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.		

When the patient is severely ill and there is real doubt about adequacy of the circulation and absorption from the IM injection site, Adrenaline 1:1000 (1mg/mL) Solution for injection may be given by intravenous injection (IV).
Intravenous adrenaline should only be administered by those experienced in the use and titration of vasopressors in their normal clinical practice (see section 4.4). In the case of intravenous adrenaline, the dose must be titrated using 50 microgram boluses according to response. This dose can only be administered using a 1 in 10,000 solution (i.e. a 1:10 mL dilution of the contents of the ampoule). Do not give the undiluted 1:1000 adrenaline solution IV.
If repeated adrenaline doses are needed, an IV adrenaline infusion is recommended, with the rate titrated according to response in the presence of continued haemodynamic monitoring.
Cardiopulmonary resuscitation
Adults
1 mg adrenaline by the intravenous or intraosseous route repeated every 3-5 minutes until return of spontaneous circulation. If injected through a peripheral line, it must be followed by flush of at least 20 mL of fluid and elevation of the extremity for 10–20 seconds to facilitate drug delivery to the central circulation.
Paediatric population
The recommended intravenous or intraosseous dose of adrenaline in children is 10 micrograms/kg. Depending on weight, such doses may need to be administered using a 1 in 10,000 solution (i.e. a 1:10 mL dilution of the contents of the ampoule). Subsequent doses of adrenaline may be given every 3–5 min. The maximum single dose is 1 mg.
Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Overdose
Signs
Overdose of Adrenaline 1:1000 (1mg/mL) Solution for injection leads to restlessness, confusion, pallor, tachycardia, bradycardia, cardiac arrhythmias and cardiac arrest.
Treatment
Treatment is primarily symptomatic and supportive. Prompt injection of a rapidly-acting alpha-adrenoceptor blocking agent such as phentolamine, followed by a beta-blocker such as propranolol, has been tried to counteract the pressor and arrhythmogenic effects of adrenaline. A rapidly-acting vasodilator such as glycetyl trinitrate has also been used.