

PACKAGE LEAFLET

Package leaflet: Information for the patient

Adrenaline Accord 0,1 mg/ml, oplossing voor injectie in een voorgevulde spuit epinephrine

Read all of this leaflet carefully before this medicine is administered to you 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 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What is <Invented name> and what it is used for
2. What you need to know before you use <Invented name>
3. How to use <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What is <Invented name> and what it is used for

<Invented name> is used in cardiopulmonary resuscitation and the treatment of sudden life-threatening allergic reactions (acute anaphylaxis).

2. What you need to know before you use <Invented name>

Do not use <Invented name>:

- 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 using <Invented name>:

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
- Cerebrovascular disease, organic brain damage or arteriosclerosis, coronary insufficiency, structural cardiac disease
- Patients taking Monoamine oxidase (MAO) inhibitors
- Patients taking concomitant medication which results in additive effects, or sensitizes the myocardium to the actions of sympathomimetic agents.

Patients who receive intravenous epinephrine require continuous monitoring, minimum by ECG, pulse oximetry and frequent blood pressure measurements.

Should be used with caution in elderly and pregnant patients.

Other medicines and <Invented name>

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-blockers, especially non-cardioselective 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), since the effects of adrenaline may be increased.
- Drugs containing catechol-O-methyltransferase (COMT) inhibitors (eg. entacapone, tolcapone) may increase the effects of adrenaline.
- Insulin or diabetes medicines taken orally, since adrenaline increases the blood sugar level.
- Alpha blockers since they antagonise the vasoconstriction and hypertension effects of adrenaline, increasing the risk of hypotension and tachycardia.

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 should only be used during pregnancy if the potential benefits justify the possible risks to the foetus.

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

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

<Invented name> 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 to use <Invented name>

Your doctor or nurse will administer <Invented name> to you.

Dose and method of administration

The dose is determined by your doctor and individually adjusted for you.

Cardiac arrest (cardiopulmonary resuscitation)

Adults: 1 mg intravenous bolus dose every 3-5 minutes.

Paediatric population (≥ 20 kg body weight): 0.01 mg/kg intravenous bolus dose. Subsequent doses of adrenaline may be given every 3–5 min. Maximum single dose is 1 mg.

Life-threatening allergic reactions in adults

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.

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 <Invented name>

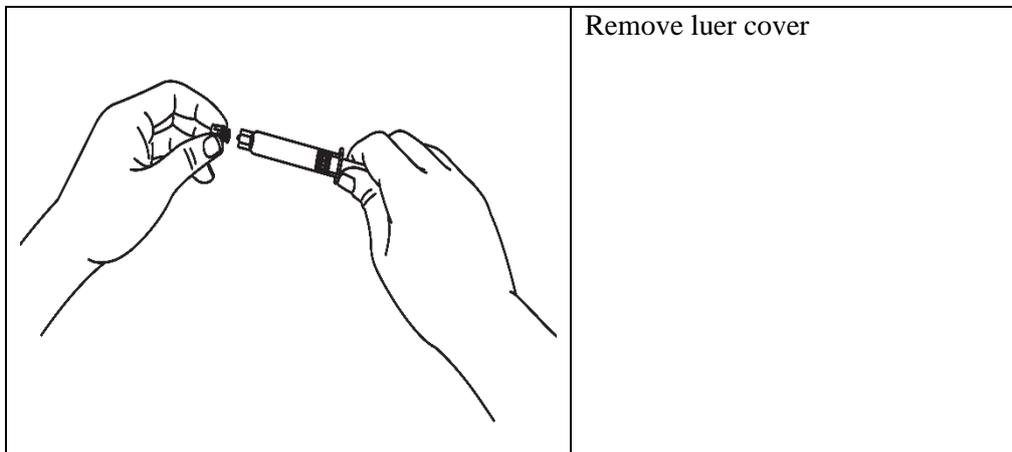
It is unlikely that you will receive too much of this medicine as it is only administered to you by your doctor or nurse.

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.

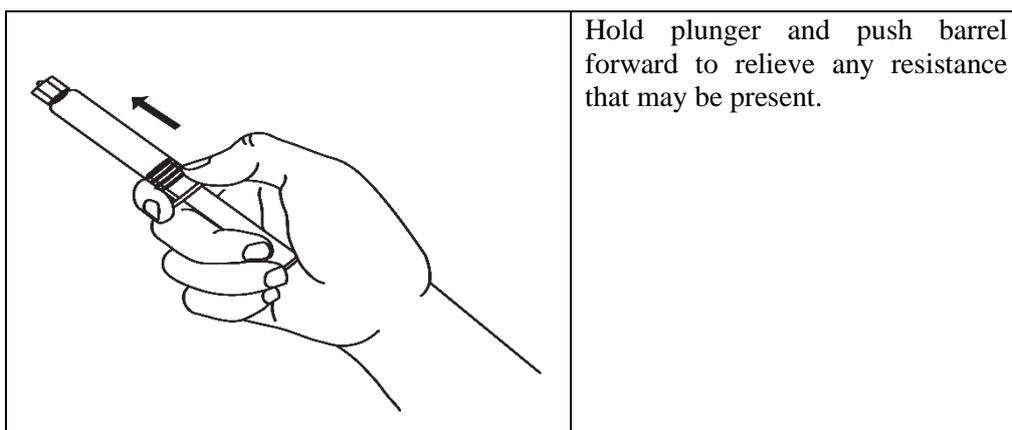
If you have any further questions on the use of this medicine, ask your doctors, pharmacist or nurse.

Instructions for the use of pre-filled syringe

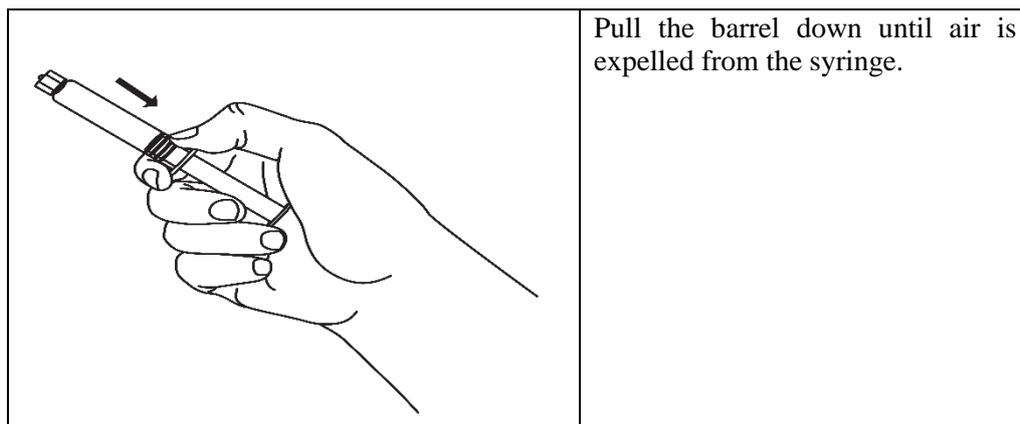
Step - 1



Step - 2



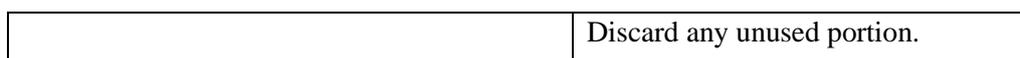
Step - 3



Step - 4



Step - 5



4. Possible side effects

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

The following side effects have been reported:

- Headache, dizziness
- Heart rate increased, increased blood pressure, heart rhythm disorders.
- Anxiety, tremor
- Hypokalaemia
- Metabolic acidosis
- Hyperglycaemia
- Anxiety, fear
- Palpitation
- Tachycardia
- Paraesthesia, cerebral haemorrhage, syncope
- Angina pectoris
- Ventricular arrhythmias, atrial fibrillation, ventricular fibrillation,
- Cardiac arrest, acute myocardial infarction, stress cardiomyopathy
- Dyspnea
- Pulmonary oedema
- Nausea
- Vomiting
- Sweating
- Weakness

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 <Invented name>

Store below 30°C.

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 <Invented name> contains

- The active substance is epinephrine (adrenaline). Each ml of solution contains 0.1 mg epinephrine (adrenaline). Each 10 ml pre-filled syringe contains 1 mg epinephrine (adrenaline).
- The other ingredients are sodium chloride, sodium metabisulphite, citric acid, sodium citrate and water for injections.

What <Invented name> looks like and contents of the pack

<Invented name> is a clear and colourless solution. It is supplied in a 10 ml clear glass pre-filled syringe having graduation marking in blue color (graduation per 0.5 ml) with plunger stopper and polypropylene plunger rod. The glass pre-filled syringe is packed in outer carton box or twist box.

The pre-filled syringe is available in pack of 1 pre-filled syringe in outer carton and 1 pre-filled syringe in twist box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare B.V.
Winthontlaan 200
3526 KV Utrecht
Nederland

Manufacturer

Accord Healthcare Polska Sp. z o.o.
Ul. Lutomierska 50
95-200 Pabianice, Lodzkie
Polen

Fundacio Privada Dau
Calle Lletra C De La Zona Franca 12-14
Poligono Industrial De La Zona Franca De Barcelona
08040 Barcelona
Spanje

Accord Healthcare Single Member S.A.
64th Km National Road Athens Lamia

320 09 Schimatari, Viotias
Griekenland

Dit medicijn is in het register ingeschreven onder nummer RVG 132671.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Nederland	Adrenaline Accord 0,1 mg/ml, oplossing voor injectie in een voorgevulde spuit
Tsjechië	Adrenaline Accord
Roemenië	Adrenalină Accord 0,1 mg/ml, soluție injectabilă în seringă preumplută
Frankrijk	ADRENALINE ACCORD 1mg/10mL solution injectable en seringue préremplie
Portugal	Adrenalina Accord
Spanje	Adrenalina Accord 0,1 mg/ml solución inyectable en jeringa precargada
Italië	Adrenalina Accord

Deze bijsluiter is voor het laatst goedgekeurd in januari 2026.

Detailed information on this medicine is available on the website of {MS/Agency}.

The following information is intended for healthcare professionals only:

Intravenous or intraosseous adrenaline should only be administered by those experienced in the use and titration of vasopressors in their normal clinical practice.

Cardiopulmonary resuscitation:

Adults

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 of the same dosage is recommended.

Paediatric population (≥ 20 kg body weight) 0.01 mg/kg using intravenous boluses. Maximum single dose is 1 mg. Subsequent doses of adrenaline may be given every 3–5 min.

If venous access is not available, intraosseous administration of the same dosage is recommended.

Acute 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. Adrenaline 0.1 mg/ml solution for injection in pre-filled syringe is not recommended for intramuscular use in acute anaphylaxis. For intramuscular administration in anaphylaxis, a 1 mg/ml solution should be used.

It is important that time is not wasted in attempting to find intravenous line if 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.

This medicinal product is not appropriate to deliver a dose of less than 2 ml and should therefore not be used in paediatric patients.

Elderly

The safety and efficacy of epinephrine (adrenaline) in age categories of elderly patients have not been well established. Dosing selection should be cautious for elderly patients who may be more sensitive for adverse events.

Incompatibilities

In compatibility studies, this medicinal product has shown to be compatible with 0.9% sodium chloride.