

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****PHARMA-Q ADRENALINE INJECTION 1 mg/ml solution for injection****Adrenaline (epinephrine) base as tartrate****Sugar free**

Read this full leaflet carefully before you are given PHARMA-Q ADRENALINE INJECTION 1 mg/ml

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- PHARMA-Q ADRENALINE INJECTION 1 mg/ml has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PHARMA-Q ADRENALINE INJECTION 1 mg/ml is and what it is used for.
2. What you need to know before you are given Pharma-Q Adrenaline Injection 1 mg/ml.
3. How PHARMA-Q ADRENALINE INJECTION 1 mg/ml will be given to you.
4. Possible side effects that you may experience.
5. How to store PHARMA-Q ADRENALINE INJECTION 1 mg/ml.
6. Contents of the pack and other information.

1. What PHARMA-Q ADRENALINE INJECTION 1 mg/ml is and what it is used for

The active substance of PHARMA-Q ADRENALINE INJECTION 1 mg/ml is:

Adrenaline (epinephrine) belongs to a group of medicines called sympathomimetic substances.

Each 1 ml contains 1 mg adrenaline (epinephrine) as the acid tartrate.

PHARMA-Q ADRENALINE INJECTION 1 mg/ml is used in life-threatening emergencies, such as acute allergic reactions

2. What you need to know before you are given PHARMA-Q ADRENALINE INJECTION 1 mg/ml

PHARMA-Q ADRENALINE INJECTION 1 mg/ml should not be administered to you:

- if you are hypersensitive (allergic) to adrenaline (epinephrine) or any of the other ingredients of PHARMA-Q ADRENALINE INJECTION 1 mg/ml (listed in section 6).
- If you are receiving mono-amine oxidase inhibitors as adrenaline (epinephrine) interacts with monoamine oxidase inhibitors and should not be given to patients receiving such treatment or within 14 days of its termination
- PHARMA-Q ADRENALINE INJECTION 1 mg/ml should not be administered in your fingers, toes, ears, nose or genitalia owing to the risk of ischaemic tissue necrosis (the death of most or all of the cells in an organ or tissue due to disease, injury, or failure of the blood supply).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Special care should be taken with PHARMA-Q ADRENALINE INJECTION 1 mg/ml if you suffer from the following:

- Parkinson's disease
- Hyperthyroidism (overactive thyroid)
- Psychoneurosis, or any other psychological disorder
- Pheochromocytoma (a tumour on your adrenal gland)
- Narrow angle glaucoma (high pressure in your eyes)
- Diabetes mellitus (high blood sugar)
- Hypokalaemia or hypercalcaemia (low blood levels of potassium or high blood levels of calcium in your body)
- Severe renal impairment (kidney problems)
- Prostatic hypertrophy (enlarged prostate) or have difficulty urinating
- Any disease of the brain, or you have suffered any brain damage
- Arteriosclerosis (narrowing and hardening of your blood vessels)
- Autonomic dysreflexia (hyperreflexia), particularly in spinal cord injury (e.g., tetraplegics)
- Shock (other than anaphylactic shock) or have lost a lot of blood
- A heart disease, heart failure, chest pains or you have an abnormal heartbeat
- Hypertension (high blood pressure) as well as most patients with dysrhythmias
- If you are elderly
- Asthma or emphysema
- If you are going to have surgery under general anaesthesia
- If you are in labour (you are having your baby)
- Phenothiazine-induced circulatory collapse or hypotension

Other medicines and PHARMA-Q ADRENALINE INJECTION 1 mg/ml

Always tell your health care provider if you are taking any other medicine. (This

includes all complementary or traditional medicines.)

Tell your doctor or health care provider if you are currently using:

- other medicines like epinephrine (adrenaline) which increase blood pressure,
- ergot alkaloids (used to treat migraines or severe headaches),
- oxytocin (used to induce labour at term and to control bleeding after delivery),
- phentolamine, guanethidine (used to reduce your blood pressure),
- propranolol (used to treat high blood pressure, irregular heartbeat or chest pains),
- general anaesthetics (used to induce a sleep-like state during surgical procedures),
- guanethidine (used to treat high blood pressure)
- monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants, including imipramine (used to treat depression),
- phenothiazines (used to treat psychosis or hallucinations),
- cardiac glycosides (used to treat heart failure),
- antihistamines (used to treat allergies),
- medicines used to treat an underactive thyroid gland,
- levodopa, entacapone (used to treat Parkinson's disease),
- corticosteroids (medicines used to treat inflammatory conditions in your body such as asthma or arthritis),
- diuretics (used to reduce water retention from your body),
- aminophylline and theophylline (medicines to help you breathe),
- insulin or oral hypoglycaemic medicines (used to treat high blood sugar).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider

for advice before PHARMA-Q ADRENALINE INJECTION 1 mg/ml is administered to you. Please tell your doctor or health care provider before being given PHARMA-Q ADRENALINE INJECTION 1 mg/ml if you are pregnant. The doctor will then decide if the injection is suitable for you.

Breastfeeding

Adrenaline (epinephrine) is distributed into breast milk. Breastfeeding should be avoided in mothers receiving PHARMA-Q ADRENALINE INJECTION 1 mg/ml.

Driving and using machines

Your ability to drive and use machines may be affected by the anaphylactic reaction, as well as by possible adverse reactions to adrenaline (epinephrine).

It is not always possible to predict to what extent PHARMA-Q ADRENALINE INJECTION 1 mg/ml, may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PHARMA-Q ADRENALINE INJECTION 1 mg/ml, affects them.

PHARMA-Q ADRENALINE INJECTION 1 mg/ml, contains

Sodium metabisulphite (anti-oxidant) (E223) which can rarely cause severe hypersensitivity reactions and bronchospasm.

The presence of sodium metabisulphite in parenteral PHARMA-Q ADRENALINE INJECTION 1 mg/ml and the possibility of allergic-type reactions should not use of the medicine when indicated for the treatment of serious allergic reactions or for other emergency situations.

3. How to receive PHARMA-Q ADRENALINE INJECTION 1 mg/ml

Your doctor will tell you how long your treatment with PHARMA-Q ADRENALINE INJECTION 1 mg/ml will last. If you have the impression that the effect of PHARMA-Q ADRENALINE INJECTION 1 mg/ml is too strong or too weak, tell your doctor or pharmacist.

The usual dose is.

By subcutaneous or intramuscular injection.

Adults: 0,2 to 0,5 ml

Children: 0,1 to 0,3 ml

If you are administered more PHARMA-Q ADRENALINE INJECTION 1 mg/ml than you should

Since a health care provider will administer PHARMA-Q ADRENALINE INJECTION 1 mg/ml, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PHARMA-Q ADRENALINE INJECTION 1 mg/ml

Since a health care provider will administer PHARMA-Q ADRENALINE INJECTION 1 mg/ml, it is unlikely that the dose will be missed.

4. Possible side effects

PHARMA-Q ADRENALINE INJECTION 1 mg/ml can have side effects.

Not all side effects reported for PHARMA-Q ADRENALINE INJECTION 1 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PHARMA-Q ADRENALINE INJECTION 1 mg/ml, please consult your health care provider for advice.

If any of the following happens, stop receiving PHARMA-Q ADRENALINE INJECTION 1 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to PHARMA-Q ADRENALINE INJECTION 1 mg/ml. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent

- Stress cardiomyopathy (a disease of the heart muscle that makes it harder for the heart to pump blood to the rest of the body)

Frequency unknown:

- Anaphylaxis (allergic reaction) possibly with severe bronchospasm (a cough with generalized wheezing)
- Hypokalaemia (when the amount of potassium in your blood is too low)
- Disturbances of glucose metabolism
- Inhibition of insulin secretion and hyperglycaemia (high blood sugar) even with low doses
- Gluconeogenesis (the reversal of the process in which glucose is broken down to produce energy)
- Lipolysis (the breakdown of fats and other natural oils to release fatty acids) and ketogenesis (a physiologically important process to produce an alternative

metabolic source of energy)

- Metabolic acidosis (occurs when acid builds up or when bicarbonate is lost)
- Psychotic states anxiety, fear, confusion
- Insomnia (inability to sleep)
- Restlessness, irritability, hallucinations, nervousness.
- Headache, tremors, dizziness
- In patients with Parkinsonian syndrome, PHARMA-Q ADRENALINE INJECTION 1 mg/ml increases rigidity and tremor
- Syncope (fainting or passing out)
- Mydriases (dilation of the pupil of the eye)
- Palpitations (feelings or sensations that your heart is pounding or racing), cardiac arrest, rapid pulse, anginal pain, acute angina attacks
- Weakness and coldness of the extremities, even with small doses and especially when given in conjunction with local anaesthetics
- Tachycardia (a fast heartbeat)
- Reflex bradycardia (If blood pressure decreases, the heart beats faster in an attempt to raise it)
- Cardiac dysrhythmias (an abnormal or irregular heartbeat)
- Potentially fatal ventricular dysrhythmias (abnormal heart rhythms that make the lower chambers of your heart twitch instead of pump) including fibrillation, especially in patients with organic heart disease or those receiving other medicines that sensitise the heart to dysrhythmias (abnormality in a physiological rhythm)
- Myocardial ischaemia (occurs when blood flow to the heart muscle is obstructed by a partial or complete blockage of a coronary artery by a buildup of plaques) and myocardial infarction (heart attack) electrocardiogram (ECG) changes including a decrease in T-wave amplitude in all leads in normal

subjects

- Subarachnoid haemorrhage (bleeding in the space that surrounds the brain). and hemiplegia (paralysis that affects only one side of your body) have resulted from hypertension, even following subcutaneous administration of usual doses of PHARMA-Q ADRENALINE INJECTION 1 mg/ml
- Bowel necrosis (the death of body tissue which occurs when too little blood flows to the tissue)
- Hypotension (low blood pressure) with dizziness, flushing and fainting
- Vasoconstriction (narrowing of blood vessels by small muscles in their walls) with resultant hypertension. The rise in blood pressure may produce cerebral haemorrhage (bleeding in the brain) and pulmonary oedema (too much fluid in the lungs), coldness of extremities may occur even with small doses.
- Reduced appetite, nausea, vomiting, hypersalivation, dry mouth.
- Difficulty in micturition(urinating), urinary retention.
- Dyspnoea (difficulty or laboured breathing), weakness, disturbances of glucose metabolism, sweating, extravasation of parenterally administered catecholamines (hormones made by your adrenal glands) may result in tissue necrosis and sloughing, pallor, necrosis may also occur in the extremities, kidneys and liver

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”,

found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of PHARMA-Q ADRENALINE INJECTION 1 mg/ml.

5. How to store PHARMA-Q ADRENALINE INJECTION 1 mg/ml

Store all medicines out of reach of children.

Store at or below 25 °C

Protect from light.

PHARMA-Q ADRENALINE INJECTION 1 mg/ml is not to be used if its colour is pinkish or darker than slightly yellow or if it contains a precipitate.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PHARMA-Q ADRENALINE INJECTION 1 mg/ml contains

- The active substance is adrenaline (epinephrine).
- The other ingredients are nitrogen, sodium chloride, sodium metabisulphite 0,1 % *m/v* as anti-oxidant, water for injection.

What PHARMA-Q ADRENALINE INJECTION 1 mg/ml looks like and contents of the pack

A clear, practically colourless, slightly acid liquid. Gradually turns dark on exposure to light and air.

1 ml clear or amber, type I glass ampoules in single pack (with syringe) or packs of 10 and 100.

Holder of Certificate of Registration

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To follow

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