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 your medical practitioner administers 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 your doctor administers 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 given PHARMA-Q ADRENALINE INJECTION

1 mg/ml if you suffer from the following

- Parkinson's disease
- Hyperthyroidism
- Psychoneurosis,
- Phaeochromocytoma (diagnosed or suspected),
- Narrow angle glaucoma (or predisposition to)
- Diabetes mellitus
- Hypokalaemia or hypercalcaemia
- Severe renal impairment
- Prostatic hypertrophy or urination difficulty;
- Cerebrovascular disease
- Organic brain damage or arteriosclerosis;
- Autonomic dysreflexia (hyperreflexia), particularly in spinal cord injury (e.g., tetraplegics);
- Shock (other than anaphylactic shock)
- Cardiogenic, traumatic, or haemorrhagic);
- Organic heart disease
- Cardiovascular disease, or cardiac dilatation (severe angina pectoris, obstructive cardiomyopathy
- Hypertension) as well as most patients with dysrhythmias.
- Anginal pain may be induced when coronary insufficiency is present
- Congestive heart failure, coronary artery disease
- Degenerative heart disease
- Ischaemic heart disease
- Phenothiazine-induced circulatory collapse or hypotension.

PHARMA-Q ADRENALINE INJECTION 1 mg/ml should be used with caution in older patients.

Adrenaline (epinephrine) should be used with extreme caution in patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease.

PHARMA-Q ADRENALINE INJECTION 1 mg/ml should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation

Children and adolescents

Your or your child must be continuously monitored after administration of PHARMA-Q ADRENALINE INJECTION 1 mg/ml

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, over-the-counter or traditional medicines.)

This is especially important with the following medicines as they may interact with your PHARMA-Q ADRENALINE INJECTION 1 mg/ml:

- Other sympathomimetic medicine (e.g., cough and cold remedies)
- Monoamine oxidase inhibitors (MAOI) or tricyclic antidepressants both used for depression
- Guanethidine, used for the rapid control of blood pressure
- Medicines to raise or lower your blood pressure including beta-blockers, e.g. propranolol, atenolol, bisoprolol and phentolamine
- Medicines used to treat mental illness like chlorpromazine, pericyazine or Fluphenazine
- Other medicines like adrenaline (epinephrine) which increase blood pressure (for example, ergot alkaloids or oxytocin).

- Corticosteroids (medicines used to treat inflammatory conditions in your body such as asthma or arthritis).
- Aminophylline and theophylline (medicines to help you breathe).
- Antihistamines (for the treatment of allergies).
- Medicines to treat an underactive thyroid gland.
- Medicines to treat Parkinson's disease (for example levodopa or entacapone)

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 machine~~ry~~s

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 deter use of the medicine when indicated for the treatment of serious allergic reactions or for other emergency situations

Sodium chloride

Nitrogen

Water for injection

3. How to use 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.

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

- 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, weakness, 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).
- Stress cardiomyopathy (a disease of the heart muscle that makes it harder for the heart to pump blood to the rest of the body)
- Palpitations, cardiac arrest, rapid pulse, anginal pain, acute angina attacks
- Hypotension (high blood pressure) with dizziness and flushing
- 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 with dizziness, flushing and fainting,
- Stimulation of α-adrenergic receptors produces vasoconstriction (narrowing of blood vessels by small muscles in their walls) with resultant hypertension. This vasoconstriction is sometimes sufficiently severe to produce gangrene when PHARMA-Q ADRENALINE INJECTION 1 mg/ml is infiltrated into the digits. The rise in blood pressure may produce cerebral haemorrhage 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**

4. 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).

5. 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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Access to the corresponding Professional Information

Can be obtained on SAHPRA's website