APPROVED PATIENT INFORMATION LEAFLET FOR
Adrenaline (Epinephrine) 1 mg/1 mL (1:1 000) Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS

Solution for injection

Epinephrine (adrenaline).

Sugar free.

Read all of this leaflet carefully before you are given ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS (epinephrine)

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS is and what it is used for.
2. What you need to know before you are given ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS.
3. How ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS will be given.

4. Possible side effects.
5. How to store ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS.
6. Contents of the pack and other information.

1. What ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS is and what it is used for

Adrenaline (epinephrine) belongs to a group of medicines called sympathomimetic substances. ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS is used in life-threatening emergencies, such as acute allergic reactions. It is an active chemical produced in the body. Epinephrine (adrenaline) acts on receptors in the body and can increase the speed and force of heart muscle contractions, relieve narrowing of the lung passages to help breathing and relieve some of the symptoms of acute allergic reaction.

2. What you need to know before you are given ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to sympathomimetic medicines, including epinephrine (adrenaline), or any of the other ingredients of ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS (see section 6.);
- if you are taking, or have taken within the last 14 days, medicines used for depression known as monoamine oxidase inhibitors (MAOIs).

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS should not be administered in your fingers, toes, ears, nose or genitalia.

Warnings and precautions

Tell your doctor or health care provider before being given ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS:

- if you have Parkinson's disease;
- if you have an overactive thyroid;
- if you suffer from any psychological disorders;
- if you have phaeochromocytoma (a tumour on your adrenal gland);
- if you have or are at risk of developing glaucoma (high pressure in your eye);
- if you have diabetes mellitus (high blood sugar);
- if you have been diagnosed with low levels of potassium or high blood levels of calcium in your body;
- if you have severe kidney problems;
- if you are male and your prostate is enlarged;
- if you have difficulty urinating;
- if you are suffering from any disease of the brain, or you have suffered any brain damage;
- if you have been told that you have atherosclerosis (narrowing and hardening of your blood vessels);
- if you have had a spinal cord injury and are suffering from over-activity of the involuntary nervous system which causes your blood pressure to be uncontrolled;
- if you are in shock or have lost a lot of blood;
- if you suffer from a heart disease, heart failure, chest pains or you have an abnormal heartbeat;
- if you have a condition called congenital long QT syndrome or problems with heart rhythm;
- if you have high blood pressure;
- if you are elderly;
- if you suffer from asthma or emphysema;

- if you are going to have surgery under general anaesthesia;
- if you are in labour (you are having your baby).

Other medicines and ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS

Always tell your health care provider if you are taking any other medicine. (This includes 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);
- 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 ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS is administered to you.

Please tell your doctor or health care provider before being given ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS if you are pregnant. The doctor will then decide if the injection is suitable for you.

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS should not be used during the second stage of childbirth or if you are breastfeeding.

Adrenaline (epinephrine) is a natural substance found in your body; therefore, this medicine is not expected to affect your ability to have children.

Driving and using machines

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS and the allergic reaction you are being treated for can affect your ability to drive a vehicle or operate machinery. Do not drive a vehicle, operate machinery, or do anything else that requires your attention while you are being treated with ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS, or until you have recovered from the allergic reaction. Ask your health care provider if you are unsure.

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS contains sodium metabisulphite

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS will be given

You will not be expected to give yourself ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS. It will be given to you by a person who is qualified to do so.

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS will be injected into a muscle or under the skin.

Your doctor will decide on the dose and will determine how many injections of ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS he/she will give you.

If you have the impression that the effect of ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS than you should

Since a health care provider will administer ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS can have side effects.

Not all side effects reported for ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS, please consult your health care provider for advice.

If any of the following happens, stop receiving ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS and tell your doctor immediately:

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- changes in the way your heart beats (such as beating faster, or skipping a beat);
- irregular or fast heartbeat, especially if you have a heart condition you were born with, that affects your heart's rhythm;
- chest pain;
- heart attack (pressure, tightness, pain, or a squeezing or aching sensation in your chest or arms that may spread to your neck, jaw or back, indigestion, shortness of breath);
- increased blood pressure which causes bleeding around the brain and paralysis;

- gangrene if ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS is injected into your fingers or toes (red/black, swollen and foul-smelling tissue);
- bowel necrosis (reduced blood flow to your bowels causing pain, tenderness, cramping, blood in your stools, diarrhoea);
- shortness of breath;
- difficulty urinating or emptying your bladder.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- metabolic acidosis (an imbalance of certain constituents in your blood);
- changes in your metabolism, such as increased sugar levels in your blood or the breakdown of fat in your body;
- abnormal thinking and perceptions (psychotic states);
- feeling anxious, scared, confused, irritated or restless;
- difficulty sleeping (insomnia);
- headache, dizziness, uncontrolled shaking (tremors);
- increased rigidity and tremor if you suffer from Parkinson’s disease;
- coldness of your hands or feet;
- low blood pressure (dizziness or fainting);
- flushing;
- dry mouth, reduced appetite, nausea (feeling sick), vomiting (being sick), increased saliva;
- increased sweating, weakness or paleness of your skin;
- tissue damage at the site of injection after repeated injections of ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS, and elsewhere in the body (for example; in the fingers and toes, liver and kidney).

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their health care provider or the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicine's regulatory authority in the country where the product is marketed either directly or via the national pharmacovigilance electronic reporting systems.

5. How to store ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS

- Store at or below 25 °C.
- Protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS contains

Each 1 mL ampoule contains 1 mg epinephrine (adrenaline) as tartrate.

The other ingredients are sodium chloride, sodium hydroxide (for pH-adjustment) (E524), sodium metabisulphite (antioxidant) (E223), tartaric acid (for pH-adjustment) (E334) and water for injection.

What ADRENALINE (EPINEPHRINE) 1 mg/1 mL (1:1 000) FRESENIUS looks like and contents of the pack

Clear, colourless to light straw-coloured solution in amber ampoules.

1 mL amber ampoule in containers of 10.

Holder of certificate of registration and manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Telephone number: +27 (0) 860 203 900

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