APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ADENOSINE 3 mg/1 ml PS FRESENIUS solution for injection

ADENOSINE 6 mg/2 ml PS FRESENIUS solution for injection

ADENOSINE 12 mg/4 ml PS FRESENIUS solution for injection

Adenosine

Sugar free

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 further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

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

1. What ADENOSINE PS FRESENIUS is and what it is used for

ADENOSINE PS FRESENIUS contains a medicine called adenosine. This belongs to a group of medicines called cardiac depressants.

ADENOSINE PS FRESENIUS works by slowing down electrical impulses between the upper and lower chambers of the heart. This slows the fast or uneven heartbeats called 'dysrhythmias'.

ADENOSINE PS FRESENIUS is used to bring your heartbeat back to normal if you have a type of dysrhythmia called ‘paroxysmal supraventricular tachycardia (SVT)’ or ‘Wolff-Parkinson-White syndrome’.

2. What you need to know before you use ADENOSINE PS FRESENIUS

Do not use ADENOSINE PS FRESENIUS:

- If you are allergic to adenosine or any of the other ingredients of ADENOSINE PS FRESENIUS (listed in section 6).
- If you have problems with your heart rhythm and do not have a pacemaker (second- or third-degree atrioventricular (AV)-block, sick sinus syndrome).
- If you have asthma.
- If you have been told you have ‘long QT syndrome’. This is a rare heart problem that can lead to a fast heartbeat and fainting.
- If you have very low blood pressure (severe hypotension).
- If you have a type of heart failure where your heart is not pumping out enough blood.

Warnings and precautions

Special care should be taken with ADENOSINE PS FRESENIUS

Tell your doctor or healthcare provider before being given the injection:

- If you have low blood volume (hypovolaemia) that is not adequately corrected by treatment with medicines.
- If you have problems with a part of your nervous system called the 'autonomic nervous system'.
- If you have narrowing of the main arteries in the neck (carotid artery). This means that not enough blood is getting to the brain (cerebrovascular insufficiency).
- If you have heart disease due to narrowing of your heart valves (stenotic valvular heart disease).
- If you have inflammation of the membrane surrounding your heart (pericarditis) or a build-up of fluid around your heart (pericardial effusion).
- If you have a left-right shunt in your heart. This will mean blood goes directly from the left side of your heart to the right side.
- If you have narrowing of the left main artery supplying blood to your heart (left main coronary stenosis).
- If you have had a recent heart attack, severe heart failure or you have had a heart transplant in the last year.
- If you have any minor problem with your heart (first degree AV-block or bundle branch block). These conditions may be temporarily aggravated when you are given ADENOSINE PS FRESENIUS.
- If you have a certain type of unusual heart rhythm (atrial fibrillation or atrial flutter) and if you have an 'accessory conduction pathway'.

- If you have been told that you have a heart problem whereby the electrical impulses in parts of your heart take longer than normal to discharge and then recharge (prolonged QT interval).
- If you have or have ever had fits or convulsions.
- If you have difficulty in breathing (bronchospasm).

Tell your doctor immediately if:

- you experience signs of stroke. This may present itself as a sudden numb or weak feeling in the face, arms, or legs. Other signs include feeling confused, problems with sight, walking, coordination or balance, problems in saying words or slurring of speech.
- you experience signs of heart attack (myocardial infarction). Severe chest pain is the usual main symptom. The pain may also travel up into your jaw, and down your left arm, or down both arms. You may also sweat, feel sick, and feel faint. A small heart attack (myocardial infarction) occasionally happens without causing pain (a 'silent myocardial infarction'). It may be truly pain-free, or sometimes the pain is mild and you may think it is just heartburn or 'wind'.

If you get a very slow heartbeat (severe bradycardia), respiratory failure, a heart problem that can be fatal (asystole), severe chest pains (angina) or very low blood pressure (severe hypotension), then treatment with ADENOSINE PS FRESENIUS should be stopped.

Children and adolescents

No controlled paediatric study has been done.

Other medicines and ADENOSINE PS FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are taking, or have received:

- Dipyridamole (a medicine used to thin the blood). Your doctor may decide you should not have ADENOSINE PS FRESENIUS or may tell you to stop taking dipyridamole 24 hours before you are given ADENOSINE PS FRESENIUS or may need to give you a lower dose of ADENOSINE PS FRESENIUS.
- Aminophylline or theophylline (medicines used to help breathing) Your doctor may tell you to stop taking it 24 hours before you are given ADENOSINE PS FRESENIUS.
- Carbamazepine (a medicine used to control seizures).
- Caffeine (sometimes found in headache medicines).

ADENOSINE PS FRESENIUS with food and drink

Food and drinks containing caffeine such as tea, coffee, chocolate and cola should be avoided for at least 12 hours before you are given ADENOSINE PS FRESENIUS.

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 healthcare provider for advice before receiving ADENOSINE PS FRESENIUS.

Pregnancy

There is no evidence that adenosine does not cause harm to the unborn baby. You should not be given ADENOSINE PS FRESENIUS if you are pregnant or think you may be pregnant, unless clearly necessary.

Breastfeeding

In the absence of information on its safe use during breastfeeding, you should not be given ADENOSINE PS FRESENIUS if you are breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent ADENOSINE PS FRESENIUS 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 ADENOSINE PS FRESENIUS affects them.

ADENOSINE PS FRESENIUS injection contains sodium

ADENOSINE PS FRESENIUS contains sodium chloride 9 mg/ml (corresponding to 3,54 mg sodium per ml, or 7,08 mg sodium per 2 ml, or l4,16 mg sodium per 6 ml). You should take this into consideration if you are on a controlled sodium diet.

3. How ADENOSINE PS FRESENIUS is given

You will not be expected to give yourself ADENOSINE PS FRESENIUS. It will be given to you be a person who is qualified to do so.

ADENOSINE PS FRESENIUS is a medicine for use in hospitals. It will be given to you by a doctor or nurse as an injection into your vein. Your heart and blood pressure will be closely monitored.

The usual dose is:

Adults (including the elderly)

- The first dose is 3 mg given over 2 seconds. This is given by rapid injection into your vein.
- If the first dose does not bring your heartbeat to normal, then you will be given a second dose. The second dose is 6 mg given as a rapid injection.
- If the second dose does not bring your heartbeat to normal, then you will be given a third dose: The third dose is 12 mg given as a rapid injection.
- You should not have any more doses after the 12 mg dose.

If you receive more ADENOSINE PS FRESENIUS than you should

Since a healthcare provider will administer ADENOSINE PS FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Tell your healthcare provider at once if you think you may have been given too much ADENOSINE PS FRESENIUS.

If you have received an overdose you will experience severe low blood pressure (hypotension), slow heartbeat (bradycardia) or your heart may stop beating and come to a standstill (asystole).

If you forget to use ADENOSINE PS FRESENIUS

Since a healthcare provider will administer ADENOSINE PS FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

ADENOSINE PS FRESENIUS can have side effects.

Not all side effects reported for ADENOSINE PS FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ADENOSINE PS FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately:

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ADENOSINE PS FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Reddening of skin with a feeling of heat (flushing)
- Slow heartbeat (bradycardia)
- Skipped heart beats or extra heartbeats
- A heart problem called an AV-block
- Shortness of breath or the urge to breathe deeply (dyspnoea)
- Feeling dizzy or light-headed
- Feeling sick (nausea)
- Feeling fearful, feeling nervous
- Headache
- Unusual skin sensations such as burning, tingling, numbing.

Less frequent side effects

- Fast or uneven heartbeats
- Severe bradycardia (very slow heartbeat)
- Being aware of your heartbeat or feeling it ‘racing’
- Severe heart problems which can be fatal (heart stops beating), or uneven heartbeat
- Breathing more quickly or more deeply than normal (hyperventilation)
- Chest pain or pressure on the chest
- Feeling pressure in your head, or weighed down in your arms
- Worsening of high blood pressure that affects the brain (intracranial hypertension)

- Blurred vision
- Metallic taste in your mouth
- Feeling of general discomfort, weakness or pain
- Sweating
- Redness, pain or swelling at the site of injection.

Frequency unknown

- Fits (convulsions)
- Severe breathlessness or problems in breathing
- Stopping breathing (respiratory arrest).
- Being sick (vomiting).

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 Reaction 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 ADENOSINE PS FRESENIUS.

5. How to store ADENOSINE PS FRESENIUS

Store all medicines out of reach of children

Keep at or below 25 °C. Do not refrigerate.

ADENOSINE PS FRESENIUS will be kept by your doctor or nurse in a safe place.

ADENOSINE PS FRESENIUS should not be used after the expiry date which is stated on the carton and on the label after 'EXP'.

The expiry date refers to the last day of that month.

ADENOSINE PS FRESENIUS is for single-use only and should be used straight away after opening. Any portion of the syringe not used at once should be disposed of.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). These measures will help protect the environment.

6. Contents of the pack and other information

What ADENOSINE PS FRESENIUS contains

- The active substance is adenosine.

Each prefilled syringe contains 3 mg of adenosine per ml.

The solution is filled into syringes of the below given container size:

3 mg in 1 mL in 1 mL syringe

6 mg in 2 mL in 5 mL syringe

12 mg in 4 mL in 5 mL syringe

- The other ingredients are sodium chloride and water for injections.

What ADENOSINE PS FRESENIUS looks like and contents of the pack

ADENOSINE PS FRESENIUS is a clear, colourless solution for injection.

ADENOSINE PS FRESENIUS is packed in cyclic olefin copolymer (COC) syringes, with a grey halobutyl plunger and closed with a Luer Lock tip cap and halobutyl stopper:

- 1 mL size single-use prefilled syringe containing 3 mg adenosine/mL solution. Available in cartons containing 10 individually boxed syringes

- 5 mL size single-use prefilled syringe containing 6 mg adenosine/2 mL solution (3 mg/mL). Available in cartons containing 10 individually boxed syringes
- 5 mL size single-use prefilled syringe containing 12 mg adenosine/4 mL solution (3 mg/mL). Available in cartons containing 10 individually boxed syringes

Vial stoppers and syringe stoppers do not contain natural rubber latex.

Not all packing sizes may be marketed.

Holder of Certificate of Registration

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ADENOSINE 3 mg/1 ml PS FRESENIUS:	50/6.2/0391
ADENOSINE 6 mg/2 ml PS FRESENIUS:	50/6.2/0392
ADENOSINE 12 mg/4 ml PS FRESENIUS:	50/6.2/0393

Access to the corresponding Professional Information

Please refer to SAHPRA’s website https://www.sahpra.org.za/Publications/Index/8