PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ADENOCOR® 6 mg/2 mL solution for injection

Adenosine

Sugar free.

Read all of this leaflet carefully before you given ADENOCOR.

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

What is in this leaflet:

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

1. What ADENOCOR is and what it is used for

ADENOCOR belongs to the group of medicines called anti-dysrhythmics (uneven heartbeat). It is a used to treat a condition when the heart beats too rapidly (paroxysmal supraventricular tachycardia or Wolff-Parkinson-White syndrome). If left untreated this condition can be life-threatening.

ADENOCOR works by slowing down the electrical impulses between the upper and lower chambers

of the heart which control the heart rhythm. This slows the fast, uneven heartbeats and allows the heart rhythm to return to normal.

2. What you need to know before you receive ADENOCOR

Do not receive ADENOCOR if you:

- Are allergic (hypersensitive) to adenosine or any of the other ingredients in ADENOCOR (listed in section 6). (Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.)
- Have chronic obstructive lung disease (asthma).
- Have a rare heart problem that can lead to a fast heartbeat and fainting (long QT syndrome).
- Have some other problems with your heart rhythm and do not have a pacemaker.
- Have severe low blood pressure.

Warnings and precautions:

Tell your doctor or health care provider before being given ADENOCOR:

- If you have a certain type of unusual heart rhythm (atrial fibrillation or atrial flutter), and particularly if you have an accessory conduction pathway.
- If you had a recent heart transplantation.
- If you have any problems with your heart.
- If you have any lung disease.

Children and adolescents:

ADENOCOR is not indicated for use in children.

Other medicines and ADENOCOR:

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

Some medicines may be affected by ADENOCOR, or may affect how well it works. These include:

- Theophylline or aminophylline (medicines used to help relieve breathing problems) and should be avoided 24 hours prior to the use of ADENOCOR.
- Dipyridamole (a medicine used to thin the blood and as prevention of a stroke in persons with a history of strokes) and should be discontinued 24 hours beforehand or the dose of ADENOCOR should be significantly reduced.
- Carbamazepine (a medicine used to treat epilepsy and seizures).
- Caffeine (sometimes found in headache medicine) and should be avoided for at least 12 hours prior to the use of ADENOCOR.

ADENOCOR with food and drink:

Tell your doctor if you eat or drink food or drinks containing large amounts of caffeine (e.g. coffee, tea, chocolate or cola). These could affect how well ADENOCOR works, and should not be eaten or drunk for at least 12 hours before you receive your injection**.**

Pregnancy and breastfeeding:

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 receiving ADENOCOR.

ADENOCOR is not recommended to be used during pregnancy or during breastfeeding.

Driving and using machines:

It is not always possible to predict to what extent ADENOCOR may interfere with your daily activities. Please ensure that you do not engage in the above activities until you are aware of the measure to which ADENOCOR affects you.

ADENOCOR contains sodium chloride:

ADENOCOR contains less than 1 mmol sodium (23 mg) per 2mL vial, that is to say it is essentially sodium free.

3. How ADENOCOR is given

Your doctor will calculate the right dose.

ADENOCOR will only be given to you in hospital.

ADENOCOR will be given to you as a rapid injection into your vein over a couple of seconds. The effect of ADENOCOR only lasts for a couple of minutes.

If you experience any unexpected or worrying side effects after being given ADENOCOR, tell your doctor immediately.

If you receive more ADENOCOR than you should:

Your doctor will administer and control the dosage. In the event of overdosage, your doctor will manage the overdosage.

If you forget to receive ADENOCOR:

Since a health care provider will administer ADENOCOR, it is unlikely that the dose will be missed.

4. Possible side effects

ADENOCOR can have side effects.

Not all side effects reported for ADENOCOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given ADENOCOR, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving ADENOCOR and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Irregular, uneven, fast or very slow heartbeat.
- A feeling of tightness across the chest.
- Severe heart problems which can be fatal.
- Problems with your breathing, such as shortness of breath, severe breathlessness, stopping breathing (respiratory arrest).
- Worsening of high blood pressure that affect the brain (intracranial hypertension).
- Stroke, including symptoms such as weakness on one side of the body, vision problems and slurred speech.
- Fainting.
- Fits (convulsions).

These may be serious side effects of ADENOCOR. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Anxiety.
- Reddening of skin with a feeling of heat (facial flushing).
- Nausea.
- Headache.
- Dizziness and light-headedness.
- Discomfort in the throat, neck or jaw.
- Unusual skin sensations such as a burning sensation.

Less frequent side effects:

- Blurred vision.

- Metallic taste in your mouth.
- Breathing more quickly or more deeply than normal (hyperventilation).
- Feeling of general discomfort, weakness or pain.
- Sweating.
- Redness, pain or swelling at the site of injection.
- Feeling uncomfortable during the injection.

Side effects with frequency unknown:

- 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 or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- 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 ADENOCOR.

5. How to store ADENOCOR

Store at or below 25 °C, protected from light.

Do not refrigerate.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

What ADENOCOR contains:

The active substance is adenosine.

Each 2 mL injection contains 6 mg of adenosine.

The inactive ingredients are sodium chloride and sterile water.

What ADENOCOR looks like and contents of the pack:

Clear, colourless solution in a clear glass vial.

ADENOCOR is packed in clear glass vials with chlorobutyl rubber closures secured with aluminium caps, containing 6 mg adenosine per 2 mL. Packs of 6 vials on plastic trays in cardboard cartons.

Holder of certificate of registration:

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th Floor

90 Bekker Road, Vorna Valley

Midrand 2196

South Africa

011 256 3700

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