

PACKAGE LEAFLET: INFORMATION FOR THE USER

Adenocor® 3mg/ml solution for injection

Adenosine

Is this leaflet hard to see or read? Phone 01 4035600 for help

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 any further questions after reading this leaflet, ask your doctor
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist

What is in this leaflet:

1. What Adenocor is and what it is used for
2. What you need to know before you are given 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 contains a medicine called adenosine. This belongs to a group of medicines called 'antiarrhythmics'. Adenocor works by slowing down electrical impulses between the upper and lower chambers of the heart. This slows the fast or uneven heartbeats called 'arrhythmias'.

Adenocor is used:

Adults

- During a test. This is to help doctors find out what type of arrhythmia (uneven heartbeat) you have
- To bring your heart beat back to normal if you have a type of arrhythmia called 'paroxysmal supraventricular tachycardia (SVT)' or 'Wolf-Parkinson-White Syndrome'

Children:

- To bring your child's heart back to normal if your child has a type of heart rhythm trouble called 'paroxysmal supraventricular tachycardia' (PSVT).

2. What you need to know before you are given Adenocor

Do not have this medicine and tell your doctor if:

- You are allergic (hypersensitive) to adenosine or any of the other ingredients of Adenocor (listed in section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have problems with your heart rhythm and do not have a pacemaker
- You have asthma

- You have been told you have 'Long QT syndrome'. This is a rare heart problem that can lead to a fast heartbeat and fainting
- You have very low blood pressure (severe hypotension)
- You have heart failure where your heart is not pumping out enough blood

Do not have this medicine if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given Adenocor.

Warnings and precautions

Take special care with Adenocor Check with your doctor, nurse or pharmacist before you have Adenocor if:

- You have a certain type of unusual heart rhythm (atrial fibrillation or atrial flutter) and in particular if you have an 'accessory conduction pathway'
- You have any other severe breathing problem such as Chronic Obstructive Pulmonary Disease (COPD)
- 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)
- You have low blood volume (hypovolaemia) that is not adequately corrected by treatment with medicines
- 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)
- You have heart disease due to narrowing of your heart valves (stenotic valvular heart disease)
- You have inflammation of the membrane surrounding your heart (pericarditis) or a build up of fluid around your heart (pericardial effusion)
- 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
- You have narrowing of the left main artery supplying blood to your heart (left main coronary stenosis)
- You have had a recent heart attack, severe failure or you have had a transplant in the last year
- You have any minor problem with your heart (first degree AtrioVentricular block or bundle branch block). These conditions may be temporarily aggravated when you are given Adenocor
- If you have an abnormal heartbeat (atrial fibrillation or flutter)
- You have a problem with a part of your nervous system called "autonomic nervous system"

Other medicines and Adenocor

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Adenocor can affect the way some other medicines work. Also some medicines can affect the way Adenocor works. In particular, check with your doctor, nurse or pharmacist if you are taking any of the following:

- Dipyridamole (medicine used to thin the blood). Make sure your doctor knows you are taking dipyridamole. Your doctor may decide you should not have Adenocor or may need to give you a lower dose of Adenocor
- Aminophylline or theophylline (medicines used to help breathing).
- Caffeine (sometimes found in headache medicines)

Adenocor 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 Adenocor.

Pregnancy and breast-feeding

Talk to your doctor or nurse before having this medicine if:

- You are pregnant, might become pregnant, or think that you may be pregnant. You should not be given Adenocor if you are pregnant or think you may be pregnant, unless clearly necessary
- You are breast-feeding. You should not be given Adenocor if you are breast-feeding.

Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding.

If you are below 18 years of age

In children with a heart rhythm trouble called 'Wolff-Parkinson-White (WPW) syndrome', Adenocor may cause some unexpected severely abnormal heart rhythm.

Adenocor contains sodium

This medicine contains less than 1mmol sodium (23mg) per 2ml, that is to say essentially "sodium free".

3. How Adenocor is given

- Adenocor 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

How much Adenocor is given

If you are not sure why you are being given Adenocor or have any questions about how much Adenocor is being given to you, speak to your doctor, nurse or pharmacist.

Adults (including the elderly)

- The first dose is 3mg 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 12mg given as a rapid injection
- You should not have any more doses after the 12mg dose

Infants and Children

Adenocor is a medicine for use in hospitals with resuscitation equipment available.

Your doctor will decide if this medicine is needed, how much should be given depending on your child's weight, and if several injections are needed.

- Your child will be closely monitored, including recording of his/her heart's electrical activity using an ECG (electrocardiogram) machine
- It will be given as an injection into your child vein by a doctor or nurse

If you have more Adenocor than you should

As this medicine is given to you by a doctor or nurse it is unlikely that you will be given too much. Your doctor will carefully work out how much Adenocor you should be given. As the length of time adenosine stays in the blood is very short, any side effects of too much Adenocor would quickly stop when the injection is stopped.

Sometimes you may need an injection of a medicine called aminophylline or theophylline to help with any side effects. If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, Adenocor can cause side effects, although not everybody gets them. While you are being given Adenocor you may have some of the following side effects:

If any of the following side effects get worse, tell your doctor or nurse and they may stop the injection:

Side effects are generally mild, of short duration and well tolerated. However severe reactions may occur. You should tell your doctor or nurse if any of them happen.

Very common (affects more than 1 person in 10)

- 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
- Uneven heartbeat
- Shortness of breath or the urge to breathe deeply (dyspnoea)
- Chest pressure/pain

Common (affects less than 1 person in 10)

- Feeling dizzy or light-headed
- Feeling sick (nausea)
- Headache
- Unusual skin sensations such as burning
- Feeling nervous

Uncommon (affects less than 1 person in 100)

- Blurred vision
- Fast heartbeat (tachycardia)
- Being aware of your heartbeat or feeling it 'racing'
- Metallic taste in your mouth
- Breathing more quickly or more deeply than normal (hyperventilation)
- Feeling pressure in your head, or weighed down in your arms
- Feeling of general discomfort/weakness or pain
- Sweating

Very rare (affects less than 1 person in 10 000)

- Severe breathlessness or problems in breathing
- Redness, pain or swelling at the site of injection
- Feeling uncomfortable during the injection
- Worsening of high blood pressure that affects the brain (intracranial hypertension)
- Very slow, fast or uneven heartbeats
- Severe bradycardia (very slow heartbeat)

Incidence unknown

- Allergic reactions including swelling of the face or throat, and skin reactions such as hives or rash
- Loss of consciousness, fainting
- Seizures (especially in predisposed patients)
- Vomiting

- Low blood pressure (sometimes severe)
- Severe heart problems which can be fatal (asystole, heart attack) especially in patients with underlying heart disease
- Severe breathing problems which can be fatal
- Spasm of the artery in the heart which may lead to a heart attack

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adenocor

This medicine will be kept by your doctor, nurse or pharmacist in a safe place where children cannot see or reach it.

Adenocor should not be used after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate.

The product is for single use only and should be used straight away after opening. Any portion of the vial not used at once should be disposed of.

Adenocor should not be used if your doctor or nurse notice any particles in the solution or any discolouration before they give you the medicine. If the appearance of the medicine has changed, the vial must be thrown away.

Medicines should not be disposed of via wastewater or household waste. The pharmacist will dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Adenocor contains

- The active substance is adenosine. Each 2ml vial of Adenocor contains 6mg of adenosine (3mg per ml).
- The other ingredients are sodium chloride and water for injections.

What Adenocor looks like and contents of the pack

Adenocor is a clear, colourless solution for injection. Each pack contains 6 vials.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or nurse.

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