

**Adenocor® 3mg/ml** solution for injection  
adenosine

sanofi aventis

**TECHNICAL INFORMATION FOR THE  
ADMINISTRATION OF ADENOCOR 3 MG/ML  
SOLUTION FOR INJECTION**

**Trade Name of Medicinal Product**

Adenocor

**Qualitative and Quantitative Composition**

Each vial contains 6 mg of adenosine per 2 ml (3mg/ml).

For excipients, see section "List of excipients".

**Pharmaceutical Form**

Solution for injection  
Clear, colourless solution

**Posology and Method of Administration**

Adenocor is intended for hospital use only with monitoring and cardiorespiratory resuscitation equipment available for immediate use. It should be administered by rapid IV bolus injection

according to the ascending dosage schedule below. To be certain the solution reaches the systemic circulation administer either directly into a vein or into an IV line. If given into an IV line it should be injected as proximally as possible, and followed by a rapid saline flush.

Adenocor should only be used when facilities exist for cardiac monitoring. Patients who develop high-level AV block at a particular dose should not be given further dosage increments.

**Therapeutic dose**

**Adult**

- Initial dose: 3 mg given as a rapid intravenous bolus (over 2 seconds).
- Second dose: if the first dose does not result in elimination of the supraventricular tachycardia within 1 to 2 minutes, 6 mg should be given also as a rapid intravenous bolus.
- Third dose: if the second dose does not result in elimination of the supraventricular tachycardia within 1 to 2 minutes, 12 mg should be given also as a rapid intravenous bolus.

Additional or higher doses are not recommended.

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**Read all of this leaflet carefully before you  
are given this medicine.**

- 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.

**In this leaflet:**

1. What Adenocor is and what it is used for
2. Before you are given Adenocor
3. How Adenocor is given
4. Possible side effects
5. How to store Adenocor
6. Further 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:**

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

**2. 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 asthma or any other severe breathing problem;
- you have very low blood pressure (severe hypotension);
- you have a type of heart failure where your heart is not pumping out enough blood;
- you have problems with your heart rhythm and do not have a pace maker (second or third degree AtrioVentricular block, sick sinus syndrome);
- you have been told you have 'Long QT syndrome'. This is a rare heart problem that can lead to a fast heart beat and fainting.

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.

**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 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 problems with a part of your nervous system called the 'autonomic nervous system';
- 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 or have ever had fits or convulsions;
- you have difficulty in breathing (bronchospasm);
- 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 heart failure or you have had a heart transplant in the last year;
- you have any minor problem with your heart (first degree AtrioVentricular block or bundle branch block). These conditions maybe temporarily aggravated when you are given Adenocor.

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 Adenocor should be stopped. If you are not sure if any of the above apply to you, talk to your doctor or nurse before being given Adenocor.

**Taking or using other medicines**

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).

**Taking 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.

**Important information about some of the ingredients of Adenocor**

**Sodium:** Adenocor injection contains 3.54 mg sodium per dose (7.08 mg/2 ml vial). This should be taken into consideration by patients on a controlled sodium diet.

### Children

No controlled paediatric study has been undertaken. Published uncontrolled studies show similar effects of adenosine in adults and children; effective doses for children were between 0.0375 and 0.25 mg/kg.

### Elderly

See dosage recommendations for adults.

### Diagnostic dose

The above ascending dosage schedule should be employed until sufficient diagnostic information has been obtained.

Method of administration: Rapid intravenous injection only.

### Pharmaceutical Particulars

#### List of Excipients

Sodium chloride  
Water for injections

#### Incompatibilities

Compatibility with other medicines is not known.

### Shelf-Life

Do not exceed the expiry date indicated on the outer packaging.  
Any portion of the vial not used at once should be discarded.

### Special Precautions for Storage

Do not refrigerate.  
Store below 30° C.

### Nature and Contents of Container

Clear, Type I glass vials with chlorobutyl rubber closures secured with aluminium caps. Packs of 6 vials in plastic trays in cardboard cartons.

### Instructions for Use/Handling

None.

### 7. Marketing Authorisation Holder

sanoï-aventis  
One Onslow Street  
Guildford, Surrey, GU1 4YS - UK

### Marketing Authorisation Number

PL 11723/0005

## 3. How Adenocor is given

### 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 3 mg given over 2 seconds. This is given by rapid injection into your vein.
- If the first dose does not bring your heart beat 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 heart beat 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.

### Children

The hospital specialist will decide if this medicine is needed and how much should be given.

### 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:

The side effects normally settle within seconds or minutes after the injection is finished but 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.
- Severe heart problems which can be fatal (asystole) or uneven heartbeat.
- Shortness of breath or the urge to breathe deeply (dyspnoea).
- Chest pain or pressure on the chest.

### 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.
- 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).

### Other side effects

- Fainting.
  - Fits (convulsions).
  - Being sick (vomiting).
  - Stopping breathing (respiratory arrest).
- If any of the above side effects get worse, tell your doctor or nurse and they may stop the injection. The side effects normally settle within seconds or minutes after the injection is finished but you should tell your doctor or nurse if any of them happen. If you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

## 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 on the label.

The expiry date refers to the last day of that month. Adenocor should not be refrigerated.

Store below 30° C.

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. Further information

### What Adenocor contains

- The active substance is adenosine. Each 2 ml vial of Adenocor contains 6 mg of adenosine (3 mg 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

Marketing Authorisation Holder:  
sanoï-aventis  
One Onslow Street  
Guildford, Surrey, GU1 4YS - UK

Manufacturer:  
SANOI AVENTIS, S.A.  
Avenida de Leganes, 62  
28925 ALCORCON (Madrid)  
Spain

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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