

**The following information is intended for healthcare professionals only: Practical information on preparation and administration of Adenocor 3mg/ml solution for injection (see also Section 3).**

**Posology and Method of Administration**

Adenocor is intended for hospital use only with monitoring and cardiorespiratory resuscitation equipment available for immediate use.

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.

**Posology**

**Rapid conversion to a normal sinus rhythm of paroxysmal supraventricular tachycardias**

**Adult**

**Initial dose:** 3mg 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, 6mg 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. 12mg should be given also as a rapid intravenous bolus.

Additional or higher doses are not recommended.

**Paediatric population**

During administration of adenosine cardio-respiratory resuscitation equipment must be available for immediate use if necessary.

Adenosine is intended for use with continuous monitoring and ECG recording during administration.

The dosing recommended for the treatment of paroxysmal supraventricular tachycardia in the paediatric population is:

- first bolus of 0.1mg/kg body weight (maximum dose of 6mg)
- increments of 0.1mg/kg body weight as needed to achieve termination of supraventricular tachycardia (maximum dose of 12mg).

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**PACKAGE LEAFLET: INFORMATION FOR THE USER**

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

Adenosine

SANOFI



If this leaflet is hard to see or read? Phone 0800 035 2525 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, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**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:**

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

**In children, Adenocor bolus is used:**

- To bring your child's heartbeat 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 if:**

- × You are allergic to adenosine or any of the other ingredients of this medicine (listed in section 6). 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 heartbeat 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.



**Warnings and precautions**

Talk to 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 may be 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.

Talk to 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'.

**Children and adolescents**

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

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



**Other medicines and Adenocor**

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take 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 tell you to stop taking dipyridamole 24 hours before you are given Adenocor or may need to give you a lower dose of Adenocor.
- Aminophylline or theophylline (medicines used to help breathing) Your doctor may tell you to stop taking it 24 hours before you are given Adenocor.
- 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.

**Adenocor injection contains sodium.**

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

Turn Over

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## Elderly

See dosage recommendations for adults.

## Method of administration

Adenosine should be administered by rapid intravenous (IV) bolus injection into a vein or into an IV line. If given into an IV line it should be injected through as proximally as possible, and followed by a rapid saline flush. If administered through a peripheral vein, a large bore cannula should be used.

## Diagnostic dose

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

## Method of administration

Rapid intravenous (IV) injection only.

## Overdose

Overdose would cause severe hypotension, bradycardia or asystole. The half-life of adenosine in blood is very short, and side effects (when they occur) would quickly resolve. Administration of IV aminophylline or theophylline may be needed. Pharmacokinetic evaluation indicates that methylxanthines are competitive antagonists to adenosine, and that therapeutic concentrations of theophylline block its exogenous effects.

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## 3. How Adenocor is given

Adenocor is always given to you by a doctor or nurse in a hospital. This is because it needs to be given as an injection into your vein. Your heart and blood pressure will be closely monitored.

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 or nurse.

### 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 6mg 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.

### Children and adolescents

Adenocor bolus 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.

If you have more of this medicine than you should, the following effects may happen:

- Very low blood pressure (severe hypotension)
- Slow heartbeat (bradycardia)
- A heart problem (asystole)

Your doctor will be monitoring your heart throughout the procedure.

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 (may affect more than 1 in 10 people)

- Reddening of skin with a feeling of heat (flushing)
- Slow heartbeat (bradycardia)
- Skipped heartbeats 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 (may affect less than 1 in 10 people)

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

### Uncommon (may affect less than 1 in 100 people)

- 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

## Incompatibilities

Compatibility with other medicines is not known.

## Shelf-Life

3 years.

Any portion of the vial not used at once should be discarded.

## Special Precautions for Storage

Do not refrigerate.

## Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### Very rare (may affect less than 1 in 10,000 people)

- 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

- Allergic reactions including swelling of the face or throat, and skin reactions such as hives or rash
- Fainting
- Fits (convulsions)
- Being sick (vomiting)
- Stopping breathing (respiratory arrest)

### Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

#### United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### Malta

You can also report side effects directly via ADR Reporting: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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 or nurse 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 after 'EXP'. The expiry date refers to the last day of that month.

Adenocor should not be refrigerated.

The medicine 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.

Do not throw away any medicines via wastewater or household waste. These measures will help 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

**Marketing Authorisation Holder:**  
Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.  
Tel: 0800 035 2525  
email: [uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

#### Manufacturer:

FAMAR HEALTH CARE SERVICES MADRID, S.A.U.  
Avda. Leganés, 62  
Alcorcón 28923 (Madrid) Spain  
Or  
Cenexi HSC Hérouville-Saint-Clair  
2 rue Louis Pasteur,  
14200 Hérouville-Saint-Clair, France

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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