

PACKAGE LEAFLET: INFORMATION FOR THE USER

Adenosine 3mg/ml Solution for Injection (6mg in 2ml)

(Referred to as Adenosine Injection in the remainder of the leaflet)

Read all of this leaflet carefully before you start to take this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



What is in this leaflet:

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

1. WHAT ADENOSINE INJECTION IS AND WHAT IT IS USED FOR

The name of your medicine is Adenosine Injection. The active ingredient in your medicine is adenosine. Adenosine belongs to a group of medicines called antiarrhythmics.

Adenosine Injection works by slowing down electrical impulse between the upper and lower chambers of the heart. This slows the fast or uneven heartbeat called arrhythmias.

Adenosine Injection is used:

- during a test. This helps doctors find out what type of arrhythmia (uneven heartbeat) you have
- to bring your heart back to normal if you have a type of arrhythmia called paroxysmal supraventricular tachycardia (PSVT) or Wolff Parkinson-White Syndrome (WPW)

In children, Adenosine Injection bolus is used:

- To bring your child's heart beat back to normal if your child have a type of heart rhythm trouble called PSVT.

2. BEFORE YOU ARE GIVEN ADENOSINE INJECTION

Do not take Adenosine Injection if you

- are allergic (hypersensitive) to adenosine or to any of the other ingredients in this medicine (see section 6. Further information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- have problems with your heart rhythm and do not have a pacemaker (second or third degree atrioventricular block, sick sinus syndrome)
- have very low blood pressure (severe hypotension)
- have asthma or any other severe breathing problem
- have a type of heart failure where your heart is not pumping out enough blood
- 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 or nurse before you are given Adenosine.

Warnings and precautions

Talk to your doctor, nurse, pharmacist before you have taken Adenosine if:

- low blood volume which is not corrected by medicines
- narrowing of your left main artery supplying blood to your heart (left main coronary stenosis)
- 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)
- narrowing of the main arteries in the neck, so not enough blood is getting to the brain
- a heart disease which is caused by the narrowing of your heart valves (stenotic valvular heart disease)
- a left-right shunt in your heart, which means blood goes directly from the left side of your heart to the right side
- problems with a part of your nervous system called the autonomic nervous system
- inflammation of the membrane surrounding your heart (pericarditis) or a build up of the fluid around your heart (pericardial effusion)
- had severe heart failure

INFORMATION FOR HEALTHCARE PROFESSIONALS

Adenosine 3mg/ml Solution for Injection

Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

Qualitative and Quantitative Composition

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

Contains sodium.

For a full list of excipients, see Section 6.1.

Pharmaceutical Form

Solution for injection (Injection).

A clear, colourless solution free from visible particles.

Therapeutic Indications

Rapid conversion to a normal sinus rhythm of paroxysmal supraventricular tachycardias, including those associated with accessory by-pass tracts (Wolff-Parkinson-White Syndrome).

Paediatric population

Rapid conversion to a normal sinus rhythm of paroxysmal supraventricular tachycardia in children aged 0 to 18 years.

Diagnostic Indications

Aid to diagnosis of broad or narrow complex supraventricular tachycardias. Although adenosine injection will not convert atrial flutter, atrial fibrillation or ventricular tachycardia to sinus rhythm, the slowing of AV conduction helps diagnosis of atrial activity.

- had a heart attack or if you have had a heart transplant in the last year
- any minor problem with your heart (first degree atrioventricular block or a bundle branch block). These conditions may be temporarily aggravated when you are given Adenosine Injection
- an unusual heart rhythm, for example your heartbeat is very fast or uneven (atrial fibrillation or atrial flutter) and in particular if you have a condition where your heart has abnormal electrical activity ('accessory conduction pathway')
- difficulty in breathing (bronchospasm)
- ever had fits or convulsions.

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 should be stopped.

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

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', Adenosine Injection may cause some unexpected severely abnormal heart rhythm.

Other medicines and Adenosine

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The following medicines can affect or be affected by treatment with Adenosine Injection:

- dipyridamole (a medicine used to thin the blood). Make sure you tell your doctor you are taking dipyridamole. Your doctor may decide you should not have Adenosine Injection or may tell you to stop taking dipyridamole 24 hours before you are given Adenosine Injection or may need to give you a lower dose.
- aminophylline or theophylline (medicines used to help breathing). Your doctor may tell you to stop taking it 24 hours before you are given Adenosine Injection.
- caffeine (sometimes found in headache medicines).

Taking Adenosine Injection with food and drink

Food and drink containing xanthines, for example tea, coffee, chocolate and cola, should be avoided for at least 12 hours before you are given Adenosine Injection.

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 Adenosine Injection unless clearly necessary
- You are breast-feeding. You should not be given Adenosine Injection.

Ask your doctor or nurse for advice before taking any medicine.

Important information about some of the ingredients of Adenosine Injection

This medicinal product contains approximately 7mg sodium per vial (2ml) i.e. essentially 'sodium-free'.

3. HOW YOU WILL BE GIVEN ADENOSINE INJECTION

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

Adenosine Injection will be given to you by a doctor or nurse as an injection. The injection will be into one of your veins. Your heart rate and blood pressure will be closely monitored.

Adults (including the elderly)

The first dose is 3mg given over 2 seconds. This is given as a 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 will be 6mg given as a rapid injection.

If the second dose does not bring your heart rate to normal then you will be given a third dose. The third dose is 12mg given as a rapid injection.

You will not be given any more doses after the 12mg dose.

Sensitisation of intra-cavitary electrophysiological investigations.

Posology and Method of Administration

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.

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.

Patients who develop high-level AV block at a particular dose should not be given further dosage increments.

Posology

Adults:

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.

Children and adolescents

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's vein by a doctor or nurse.

If you have more Adenosine Injection than you should

This medicine is given to you by your doctor or nurse. It is unlikely that you will be given too much. Your doctor will carefully work out how much Adenosine Injection 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.

The length of time Adenosine stays in the blood is very short. Any side effects of too much Adenosine Injection would quickly stop when the injection is stopped. You may be given an injection of a medicine called theophylline to help with any side effects.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Adenosine Injection can cause side effects, although not everybody gets them. The following side effects may be experienced when taking Adenosine Injection.

If any of the 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)

- a slow heartbeat (bradycardia)
- skipped heartbeats or extra heartbeats
- a heart problem called an atrioventricular block where the heart starts to beat slowly
- severe heart problems which can be fatal (asystole) or uneven heartbeat
- shortness of breath or the urge to breathe deeply (dyspnoea)
- reddening of the skin with a feeling of heat (flushing)
- chest pain or pressure on the chest.

Common (affects less than 1 person in 10)

- headache
- paraesthesia
- dizziness, light-headedness
- feeling nervous
- nausea (feeling sick)
- unusual skin feelings, such as burning.

Uncommon (affects less than 1 person in 100)

- feeling pressure in your head or a weighed down feeling your arms
- blurred vision
- metallic taste in your mouth
- being aware of your heartbeat or feeling it 'racing' (palpitations)
- sweating
- discomfort in the leg, arm or back
- feeling of general discomfort, weakness or pain
- breathing more quickly or more deeply than normal (hyperventilation).

Very rare side effects (affects less than 1 person in every 10,000)

- severe bradycardia (very slow heartbeat)
- very slow, fast or uneven heartbeats
- 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).

Frequency not known:

- anaphylactic reaction (including angioedema and skin reactions such as urticaria and rash)
- loss of consciousness or fainting
- vomiting (feeling sick)
- convulsions
- low blood pressure
- your heart does not work properly to circulate blood around your body (cardiac arrest). This can be fatal
- a severe heart problem, where the heart stops pumping blood around the body (asystole). This can be fatal

- your lungs do not work properly to provide enough oxygen to your blood
- stopping breathing (respiratory arrest).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:

HPRA Pharmacovigilance

Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971 Fax: +353 1 6762517

Website: www.hpra.ie e-mail: medsafety@hpra.ie

Malta ADR Reporting

Website: 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 ADENOSINE INJECTION

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate.

The product should be used immediately after opening. Any portion of the vial not used at once should be disposed of.

Do not use if any particles or discolouration are noticed in the solution. If the appearance of the vial has changed the vial must be thrown away.

Medicines should not be disposed of via wastewater or household waste. Your doctor or nurse will dispose of any unused medicine. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Adenosine 3mg/ml (6mg in 2ml) Solution for Injection contains

The active ingredient is adenosine.

Each 2ml vial contains 6mg of adenosine.

The other ingredients are sodium chloride and water for injections.

What Adenosine 3mg/ml (6mg in 2ml) Solution for Injection looks like and the contents of the pack

Adenosine is a clear, colourless solution for injection.

Adenosine 3mg/ml (6mg in 2ml) Solution for Injection is available in packs of 6 single use glass vials.

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham LL13 9UF, UK

Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham LL13 9UF, UK

Other formats: To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Adenosine 3mg/ml (6mg in 2ml) Solution for Injection	PL 29831/0457

This is a service provided by the Royal National Institute of Blind People.

For patients in Malta or the Republic of Ireland please call UK +44 1978 661261

This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Adenosine 3mg/ml Solution for Injection

Ireland: Adenosine 3mg/ml Solution for Injection

Malta: Adenosine 3mg/ml Solution for Injection

Germany: Adenosin Altamedics 3mg/ml Injektionslösung

This leaflet was last revised in 04/2019

105565/5

 WOCKHARDT

Additional or higher doses are not recommended.

Paediatric population:

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

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

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

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf Life

Unopened: 36 months.

The product should be used immediately after opening.

Special precautions for storage

Store below 25°C. Do not refrigerate.

Nature and contents of container

Clear, neutral type I glass vials (2ml) sealed with chlorobutyl rubber closures.

Packs of 6 vials packed in a PVC tray in a cardboard carton.

Special precautions for disposal

Do not use if any particles or discolouration are noticed in the solution.

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

Marketing Authorisation Holder Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Marketing Authorisation Number

UK PL 29831/0457

Ireland PA 1339/34/1

Malta MA 154/10601

Date of Revision of Text April 2019

105565/5

 WOCKHARDT