

Package leaflet: Information for the patient

Adenosine 3mg/ml Solution for Injection

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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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



1. What Adenosine Solution for Injection is and what it is used for

Adenosine 3mg/ml Solution for Injection (called Adenosine Solution for Injection throughout the rest of this leaflet) belongs to a group of medicines called antiarrhythmics.

Antiarrhythmics are used to treat an irregular heartbeat (arrhythmias). Adenosine Solution for Injection is used during hospital tests to help doctors or nurses determine what type of irregular heartbeat you have. It works by slowing down electrical impulses in your heart, in turn, slowing down either a fast or irregular heartbeat. In children, Adenosine Solution for Injection is used to bring your child's heartbeat back to normal if your child has a type of heart rhythm problem called 'paroxysmal supraventricular tachycardia' (PSVT). You will usually be in hospital when you receive this medicine.



2. What you need to know before you are given Adenosine Solution for Injection Do not have Adenosine Solution for Injection

- if you are allergic to adenosine or any of the other ingredients of this medicine (listed in section 6);
- if you have an irregular heart rhythm and do not currently have a pacemaker fitted;
- if you have asthma or any other severe breathing problems;
- if you have a disorder that affects the heart's electrical activity (Long QT syndrome);
- if you have very low blood pressure (severe hypotension);
- if you have a type of heart failure where your heart does not pump out enough blood;
- if you are below 18 years of age. In children with a heart rhythm problem called 'Wolff-Parkinson-White (WPW) syndrome', Adenosine Solution for Injection may cause some unexpected severely abnormal heart rhythm.

Tell your doctor or nurse if any of the following apply to you:

- if you have recently had a heart attack, heart failure, or you have had a heart transplant within the last year;
- if you have a low blood volume level that has not been corrected by either treatment or medication;
- if you have a type of heart disease caused by the narrowing of your heart valves;
- if your heart is inflamed, enlarged, or you have fluid around your heart;
- if you have seizures or convulsions (fits);
- if you have difficulty breathing;
- if you suffer from problems with your autonomic nervous system;
- if you suffer from a narrowing of the main

arteries in your neck (carotid arteries) that prevents sufficient blood getting to your brain;

- if you have a known heart defect;
- if you have an unusual heart rhythm (atrial fibrillation or flutter).

Using other medicines

Make sure your doctor or nurse knows if you are taking, or have recently taken, any of the medicines listed here:

- **Dipyridamole** (used to thin the blood); taking dipyridamole at the same time as Adenosine Solution for Injection will increase the effect of adenosine on the body. Your doctor or nurse may decide not to give you Adenosine Solution for Injection, may tell you to stop taking dipyridamole 24 hours before you are given Adenosine Solution for Injection, or they may lower the dose.
- **Aminophylline** and **theophylline** (used to help breathing difficulties), or medicines containing **Xanthines (caffeine)**, which are found in certain medicines used to treat headaches. Your doctor may tell you to stop taking these medicines 24 hours before you are given Adenosine Solution for Injection.
- Medicines that affect the rate at which your heart conducts electrical impulses such as **calcium channel blockers** e.g. diltiazem and amlodipine, **beta-adrenergic blocking agents** e.g. propranolol and metoprolol and **centrally acting agents** e.g. clonidine and guanfacine.

Please also tell your doctor or nurse if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

Taking Adenosine Solution for Injection with food and drink

- Where possible, do not drink or eat products containing caffeine, such as tea, coffee, chocolate, or cola, for at least 12 hours before you are given Adenosine Solution for Injection.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before they give you this medicine.
- You should not be given this medicine if you are breast-feeding.

Important information about some of the other ingredients in Adenosine Solution for Injection

- Your medicine contains **sodium (salt)**. This medicinal product contains 3.54mg (0.15mmol) of sodium (salt) per 1ml of solution. To be taken into consideration by patients on a controlled sodium (salt) diet.



3. How you will be given Adenosine Solution for Injection

You will usually be in hospital when you are given Adenosine Solution for Injection. You will be given it by a doctor or nurse, as an injection, into your vein. Your heart and blood pressure will be closely monitored.

Adults and the elderly

- The usual dose is 3mg (1ml) given over 2 seconds.
- If the first dose does not bring your heartbeat back to normal within 1-2 minutes, you will be given a second dose of 6mg (2ml).
- If the second dose does not bring your heartbeat back to normal within 1-2 minutes, you will be given a third dose of 12mg (4ml).
- You should not be given any more doses after the 12mg (4ml) dose.

Infants and Children

Adenosine Solution for Injection 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 the 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 are given too much Adenosine Solution for Injection

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too much. However, if you are given too much medicine, the following side effects may occur:

- an extreme lowering in blood pressure;
- a lowering in heart rate;
- a heart problem.

Adenosine stays in the blood for a very short period of time. Therefore, any side effects would soon subside once the injection has been stopped. You may be given a medicine called aminophylline or theophylline to help with any side effects experienced.

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



4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects after you have been given your medicine, tell your doctor or nurse immediately. If you are not in hospital, you MUST GO straight away.

- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**
- **Severe chest pain.**
- **An extreme lowering in heart rate.**
- **An extreme lowering in blood pressure.**
- **Respiratory failure.**

Very common side effects (may affect more than 1 in 10 people):

- slow beating of your heart
- chest pain or pressure on the chest
- flushing (sudden reddening of the skin accompanied by the feeling of heat)
- shortness of breath or the urge to take a deep breath
- skipped heartbeats or extra heartbeats
- a delayed, slow and irregular heartbeat

Common side effects (may affect up to 1 in 10 people):

- headache
- nausea (feeling sick)
- dizziness or feeling light headed
- apprehension (feeling nervous)
- burning sensation of the skin

Uncommon side effects (may affect up to 1 in 100 people):

- feeling pressure in your head
- blurred vision
- metallic taste in your mouth
- feeling of general discomfort, weakness or pain
- sweating
- hyperventilation (breathing more quickly or more deeply than normal)
- palpitations (the awareness of an increased, irregular heartbeat)
- increased heart rate or arrhythmia

Very rare side effects (may affect up to 1 in 10,000 people):

- intracranial hypertension (increased high blood pressure around the brain)
- fast, slow or uneven heartbeat
- difficulty breathing

Other side effects which may occur:

- fainting or loss of consciousness

- convulsions (fits)
 - vomiting (being sick)
 - cardiac arrest (a sudden loss of heart function)
 - asystole (a severe and fatal heart problem)
- Very rare effects which may occur at the site of injection (affecting up to 1 in 10,000 people):**
- redness
 - itching
 - pain
 - abscesses
 - swelling
 - swollen and painful veins

You will be observed by medical staff at all times, whilst being given Adenosine Solution for Injection, to monitor the effects on your heart.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.



5. How to store Adenosine Solution for Injection

This medicine will be stored, by your doctor, nurse or pharmacist, out of the sight and reach of children.

This medicine should not be used after the expiry date stated on the carton and vial label. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

This product is for single use only. Once your doctor or nurse has opened the vial, it should be used immediately. Any remaining Adenosine Solution for Injection must be thrown away by the doctor or nurse.



6. Contents of the pack and other information

What Adenosine Solution for Injection contains

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

What Adenosine Solution for Injection looks like and contents of the pack

Adenosine Solution for Injection (Adenosine Injection) is a clear, colourless solution in a clear, glass vial. Each vial contains 2ml of medicine. This product is available in cartons containing 6 x 2ml vials.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited, Capital House, 1st Floor, 85 King William Street, London EC4N 7BL, UK.

Tel: 00 44 (0)1283 495280

Fax: 00 44 (0)1283 495290

Email: medinfo@focuspharma.co.uk

Manufacturer

Vianex S.A., Plant A, 12km National Road Athinon-Lamias, Metamorfofi Attiki, 14451, Greece.

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

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

United Kingdom: Adenosine 3mg/ml Solution for Injection

Ireland: Adenosine 3mg/ml Solution for Injection

Greece: ADENORYTHM® 3mg/ml □□□□□μ□

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Other sources of information

For information in large print, audio CD or Braille please telephone 00 44 (0)1283 495 280 or email medinfo@focuspharma.co.uk.

Technical Leaflet intended for healthcare professionals only

ADENOSINE 3MG/ML SOLUTION FOR INJECTION

GENERAL INFORMATION

Adenosine 3mg/ml Solution for Injection is for single use only. Any portion of the vial, not used at once, should be discarded.

THERAPEUTIC INDICATIONS

Adenosine 3mg/ml Solution for Injection is indicated in adults and children aged 0 to 18 years.

Adults

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

Diagnostic Indications

Aid to diagnosis of broad or narrow complex supraventricular tachycardias. Although Adenosine 3mg/ml Solution for Injection will not convert atrial flutter, atrial fibrillation or ventricular tachycardia to sinus rhythm, the slowing of AV conduction helps diagnosis of atrial activity.

Sensitisation of intra-cavitary electrophysiological investigations.

Paediatric population

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

POSODOLOGY AND METHOD OF ADMINISTRATION

Adenosine 3mg/ml Solution for Injection is intended for hospital use only with monitoring and cardiorespiratory resuscitation equipment available for immediate use, if necessary.

Method of administration

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.

Adenosine 3mg/ml Solution for Injection 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: 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 3mg/ml Solution for Injection, cardio-respiratory resuscitation equipment must be available for immediate use if necessary. Adenosine 3mg/ml Solution for Injection 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).

Elderly

See dosage recommendations for adults.

Diagnostic dose

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

