

## Package leaflet: Information for the patient

# Adenosine 3mg/ml Solution for Injection (Adenosine)

Read all of this leaflet carefully before you start using 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.

This product will be referred to as Adenosine solution for Injection from here on.

### What is in this leaflet:

1. What Adenosine solution for injection is and what it is given for
2. What you need to know before you are given Adenosine solution for injection
3. How you are 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 given for



Adenosine solution for injection contains a medicine called adenosine. This belongs to a group of medicines called 'antiarrhythmics'.

Adenosine solution for injection works by slowing down electrical impulses between the upper and lower chambers of the heart. This slows the fast or uneven heartbeats called 'arrhythmias'. In children, Adenosine Solution for Injection is used to bring your child's heart beat back to normal if your child have a type of heart rhythm trouble called 'paroxysmal supraventricular tachycardia' (PSVT).

### Adenosine solution for injection is given:

- 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. What you need to know before you are given Adenosine solution for injection

### You should not be given Adenosine solution for injection:

- 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
- if you have asthma or any other severe breathing problem
- if you have very low blood pressure (severe hypotension)
- if you have heart failure where your heart is not pumping out enough blood
- if you have problems with your heart rhythm and do not have a pace maker (second or third degree AtrioVentricular block, sick sinus syndrome)
- if 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
- if you are below 18 years of age. In children with a heart rhythm trouble called 'Wolff-Parkinson-White (WPW) syndrome', Adenosine Solution for Injection may cause some unexpected severely abnormal heart rhythm.

You should not be given 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 solution for injection.

### Warnings and precautions

**Talk to your doctor or nurse before you are given Adenosine solution for injection 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 a condition called long QT syndrome (prolonged QT interval)
- you have low blood volume (hypovolemia) that is not adequately corrected by treatment
- 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).
- you have or have ever had fits or convulsions
- you have difficulty in breathing (bronchospasm)
- you have narrowing of your heart valves (stenotic valvular heart disease)
- you have inflammation of the membrane surrounding your heart (pericarditis) or a buildup 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 Adenosine solution for injection.

Your doctor will stop the treatment with adenosine if you experience any serious side effect.

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

### Other medicines and Adenosine solution for injection

Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Adenosine solution for injection can affect the way some other medicines work. Also some medicines can affect the way Adenosine solution for injection works.

In particular, check with your doctor or nurse 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 Adenosine solution for injection or may tell you to stop taking dipyridamole 24 hours before you are given Adenosine solution for injection or may need to give you a lower dose of Adenosine solution for injection
- Aminophylline or theophylline (medicines used to help breathing). Your doctor may tell you to stop taking it 24 hours before you are given Adenosine solution for injection
- Caffeine (sometimes found in headache medicines).

### Adenosine solution for injection with food, drink and alcohol

Food and drinks containing caffeine such as tea, coffee, chocolate and cola should be avoided 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 taking this medicine.

Pregnancy:

- you are pregnant, might become pregnant, or think that you may be pregnant. You should not be given Adenosine solution for injection if you are pregnant or think you may be pregnant, unless clearly necessary.

Breast-feeding:

- you are breast-feeding. You should not be given Adenosine solution for injection if you are breast-feeding.

### Adenosine solution for Injection contains sodium:

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

## 3. How you are given Adenosine solution for injection

- Adenosine solution for injection 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 Adenosine solution for injection is given

If you are not sure why you are being given Adenosine solution for injection or have any questions about how much Adenosine solution for injection is being given to you, speak to your doctor or nurse.

### Use in 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 heart beat to normal then you will be given a second dose. The second dose is 6 mg given as a rapid injection

Turn Over

## Healthcare Professional's Information Leaflet

The following information is extracted from the SPC.

### Technical information for the administration of Adenosine 3mg/ml solution for injection.

#### TRADE NAME OF THE MEDICINAL PRODUCT

Adenosine 3 mg/ml solution for Injection.

#### QUALITATIVE AND QUANTITATIVE COMPOSITION

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

#### PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless solution free from visible particles.

#### Posology and method of administration

Adenosine Solution for Injection is intended for hospital use only with monitoring and cardiorespiratory resuscitation equipment available for immediate use.

#### 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 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.

#### Posology

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.

Adenosine solution for 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.

Paediatric population:

The safety and efficacy of adenosine in children aged 0-18 years old have not been established. No data are available. No controlled paediatric study has been undertaken.

Turn Over

- if the second dose does not bring your heart beat 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.

#### Use in 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 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.

Adenosine has not been tested in children and there are only limited data.

#### If you are given more Adenosine solution for injection than you should

As this medicine is given to you by a doctor or nurse it is unlikely that you will be given more than you require. Your doctor will carefully work out how much Adenosine solution for 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.

As the length of time adenosine stays in the blood is very short, any side effects of Adenosine solution for injection 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, this medicine can cause side effects, although not everybody gets them. While you are being given Adenosine solution for injection you may have some of the following side effects:

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

#### Very common

**(may affect more than 1 in 10 people)**

- 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

**(may affect up to 1 in 10 people)**

- feeling dizzy or light-headed
- feeling sick (nausea)
- headache
- unusual skin sensations such as burning
- feeling nervous.

#### Uncommon

**(may affect up to 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)
- rise in the pressure inside the skull
- feeling of general discomfort, weakness or pain
- sweating.

#### Very rare

**(may affect up to 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
- very slow heart beat (severe bradycardia).

#### Not known:

**(frequency cannot be estimated from the available data)**

- severe heart problems which can be fatal (asystole) or uneven heartbeat
- 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.

#### Reporting of side effects

If you get any side effects, talk to your doctor or nurse. 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

### 5. How to store Adenosine solution for injection

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

This medicinal product does not require any special storage conditions.

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.

Do not use this medicine 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. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Adenosine solution for injection contains

- the active substance is adenosine. Each 2ml vial of Adenosine solution for injection contains 6mg of adenosine (3 mg 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 is a clear, colourless solution for injection.

Each pack contains 6 vials.

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder:

Mercury Pharmaceuticals Ltd,  
Capital House, 85 King William Street, London EC4N 7BL, UK

##### Manufacturer:

VALDEPHARM  
Parc Industriel d'incarville, 27106 Val de Reuil, 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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Published uncontrolled studies show similar effects of adenosine in adults and children: effective doses for children were between 0.0375 and 0.25mg/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 Injection

##### Incompatibilities

Compatibility with other medicines is not known.

##### Shelf life

24 months.

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

##### Special precautions for storage

This medicinal product does not require any special storage conditions.

##### Nature and contents of container

Clear, type I glass vials with chlorobutyl rubber stoppers secured with aluminium caps with flip-off seals.

Pack of 6 vials in a plastic tray.

##### Special precautions for disposal and handling

None.

#### MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Ltd,  
Capital House, 85 King William Street, London EC4N 7BL, UK

#### MARKETING AUTHORISATION NUMBER

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