

PACKAGE LEAFLET: INFORMATION FOR THE USER

Adenosine 30mg/10ml Solution for Infusion

(Referred to as Adenosine Infusion 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 nurse
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 nurse.

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1. What Adenosine Infusion and what it is used for
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1. WHAT ADENOSINE INFUSION IS AND WHAT IT IS USED FOR

The name of your medicine is Adenosine Infusion. The active ingredient in your medicine is adenosine. Adenosine belongs to a group of medicines called coronary vasodilators.

This medicine is for diagnostic use only.

Adenosine Infusion is given before a test called “myocardial perfusion imaging” to look at your heart. During this test you are given a medicine called a “radiopharmaceutical”.

Adenosine Infusion works by opening up your heart’s blood vessels and allowing blood to flow more freely. This allows the radiopharmaceutical medicine to get into your heart. The doctor can see your heart and assess your heart condition. This is used if you are not capable of exercise or if an exercise stress test is not possible.

2. BEFORE YOU ARE GIVEN ADENOSINE INFUSION

You should not be given Adenosine Infusion 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 unstable angina which is not controlled by medicine
- 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.
- are taking a medicine called dipyridamole (used to thin the blood).

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.

Take special care with Adenosine Infusion if you have

- low blood volume (hypovolaemia) which is not corrected by medicines
- narrowing of your left main artery supplying blood to your heart (left main coronary stenosis)
- 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
- 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
- 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')
- a very slow heartbeat (severe bradycardia)
- difficulty in breathing (bronchospasm)
- ever had fits or convulsions.

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

Taking other medicines

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

Infusion:

- dipyridamole (a medicine used to thin the blood). Make sure you tell your doctor you are taking dipyridamole. Your doctor will either tell you to stop taking it 24 hours before you are given Adenosine Infusion or you may be given a lower dose.
- aminophylline, theophylline or other xanthines (medicines used to help breathing). Make sure you tell your doctor you are taking any of these medicines. Your doctor will tell you to stop taking them 24 hours before you are given Adenosine Infusion.

Taking Adenosine Infusion 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 Infusion.

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 Infusion unless clearly necessary

- You are breast-feeding. You should not be given Adenosine Infusion.

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

If you are below 18 years of age

The use of Adenosine Infusion in children and adolescents has not been sufficiently studied.

Important information about some of the ingredients of Adenosine Infusion

This medicinal product contains approximately 36mg sodium per vial (10ml). To be taken into consideration by patients on a controlled sodium diet.

3. HOW YOU WILL BE GIVEN ADENOSINE INFUSION

Adenosine Infusion is a medicine for use in hospitals.

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

Adults

The dose you will be given will depend on your weight.

The usual dose is 140 micrograms per kilogram of bodyweight. This is given over a period of six minutes through an infusion pump (a slow injection into a vein).

Children

Adenosine Infusion is not recommended for use in children.

If you have more Adenosine Infusion 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 Infusion 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 would quickly stop when the infusion 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 Infusion can cause side effects, although not everybody gets them.

The following side effects may be experienced when taking Adenosine Infusion. **If any of the side effects get worse, tell your doctor or nurse immediately and they will decide if you should continue the infusion or not.**

The side effects normally settle within seconds or minutes after the infusion is finished but you should tell your doctor or nurse if any of them happen.

Very common (affects more than 1 user in 10)

- reddening of the skin with a feeling of heat (flushing)
- shortness of breath or the urge to breathe deeply (dyspnoea)
- headache
- chest pain or pressure on the chest
- abdominal discomfort.

Common (affects less than 1 user in 10):

- feeling dizzy, or light-headed
- Unusual skin sensations such as numbness, tingling, prickling, burning or creeping on the skin (paraesthesia)
- low blood pressure
- a heart problem called an atrioventricular block
- fast or irregular heartbeat (disorders of cardiac rhythm)
- dry mouth
- discomfort in throat, jaw or neck.

Uncommon (affects less than 1 user in 100):

- metallic taste in your mouth
- sweating
- discomfort in leg, arm or back
- feeling of weakness or pain, or of general discomfort
- feeling nervous
- slow heartbeat (bradycardia).

Rare (affects less than 1 user in 1,000)

- difficulty in breathing (bronchospasm)
- blocked nose
- feeling drowsy
- blurred vision
- ringing in the ear (tinnitus)
- feeling a sudden need to urinate
- nipple discomfort
- tremors.

Very rare side effects (affects less than 1 user in 10,000):

- severe breathlessness or problems in breathing
- redness, pain or swelling at the site of injection.

Other side effects (frequency cannot be estimated from the available data):

- severe heart problems which can be fatal (asystole) or uneven heartbeat
- fits (convulsions)
- fainting
- stopping breathing (respiratory arrest)
- feeling sick (nausea) or being sick (vomiting).

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 at
<http://www.mhra.gov.uk/yellowcard>

Ireland: HPRa Pharmacovigilance,
Earlsfort Terrace, IRL – Dublin 2;
Tel: 353 1 6764971
Fax: 353 1 6762517
Website: <http://www.hpra.ie>
e-mail: <mailto:medsafety@hpra.ie>

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

5. HOW TO STORE ADENOSINE INFUSION

Keep out of the reach and sight of children.

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

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. FURTHER INFORMATION

What Adenosine 30mg/10ml Solution for Infusion contains

The active ingredient is adenosine.

Each 10ml vial contains 30mg of adenosine (3mg/ml).

The other ingredients are sodium chloride and water for injections.

What Adenosine 30mg/10ml Solution for Infusion looks like and the contents of the pack

Adenosine is a clear, colourless solution for infusion.

Adenosine 30mg/10ml Solution for Infusion 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 30mg/10ml Solution for Infusion	PL 29831/0456

This is a service provided by the Royal National Institute of Blind People.
For patients in the Republic of Ireland please call 052 6186000.

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

UK: Adenosine 30mg/10ml Solution for Infusion

Ireland: Adenosine 30mg/10ml Solution for Infusion (Not marketed in Ireland)

Poland: Adenosine Infusion Wockhardt

Germany: Adenosin Altamedics 30mg/10ml Infusionslösung

This leaflet was last revisited in 10/2014

INFORMATION FOR HEALTHCARE PROFESSIONALS

Adenosine 30mg/10ml Solution for Infusion

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

Qualitative and Quantitative Composition

Each vial contains 30mg of adenosine per 10ml (3mg/ml).

Excipient: each vial contains approximately 36 mg of sodium per vial (10ml).

For a full list of excipients, see Section 6.1.

Pharmaceutical Form

Solution for infusion.

A clear, colourless solution free from visible particles

Therapeutic indications

Intravenous (IV) adenosine infusion is a coronary vasodilator for use in conjunction with radionuclide myocardial perfusion imaging in patients who cannot exercise adequately or for whom exercise is inappropriate.

Posology and method of administration

Adenosine infusion is intended for use in hospitals with monitoring and cardio-respiratory resuscitation equipment available for immediate use if necessary. It should be administered following the same procedure as for exercise testing where facilities for cardiac monitoring and cardio-respiratory resuscitation are available. During administration of adenosine infusion continuous ECG control is necessary as life-threatening arrhythmia might occur. Heart rate and blood pressure should be monitored every minute.

Adults:

1. Adenosine infusion should be administered undiluted as a continuous peripheral intravenous infusion at a dose of 140 µg/kg/min for six minutes using an infusion pump. Separate venous sites for adenosine infusion and radionuclide administration are recommended to avoid an adenosine bolus effect.
2. After three minutes of adenosine infusion, the radionuclide is injected to ensure sufficient time for peak coronary blood flow to occur. The optimal vasodilator protocol is achieved with six minutes of adenosine infusion.
3. To avoid an adenosine bolus effect, blood pressure should be measured in the arm opposite to the adenosine infusion.

The table below is given as a guide for adjustment of the infusion rate of undiluted adenosine infusion, in line with bodyweight (total dose 0.84 mg/kg).

Patient Weight (kg)	Infusion Rate (ml/min)
45-49	2.1
50-54	2.3
55-59	2.6
60-64	2.8
65-69	3.0
70-74	3.3
75-79	3.5
80-84	3.8
85-89	4.0
90-94	4.2
95-99	4.4
100-104	4.7

Paediatric population:

The safety and efficacy of adenosine in children aged 0 to 18 years have not been established. Currently available data are described in section 5.1 (SmPC) but no recommendation on a posology can be made.

Elderly:

See dosage recommendations for adults.

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 (10ml) 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 29831/0456

Ireland: PA 1339/35/1

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