

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.
- 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.



In this leaflet:

1. What Adenosine Infusion and what it is used for
2. Before you are given Adenosine Infusion
3. How you will be given Adenosine Infusion
4. Possible side effects
5. How to store Adenosine Infusion
6. Further information

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

Do not have this medicine and tell your doctor if you:

- are allergic (hypersensitive) to adenosine or to any of the other ingredients in 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.
- have very low blood pressure (severe hypotension).
- have unstable angina which is not controlled by treatment with medicine.
- have asthma or any other severe breathing problem.
- are taking a medicine called dipyridamole (used to thin the blood).
- have a type of heart failure where your heart is not pumping out enough blood
- have problems with your heart rhythm and do not have a pacemaker (second or third degree atrioventricular block, sick sinus syndrome)
- 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 Infusion.

Warnings and Precautions

Check with your doctor or nurse before you have Adenosine Infusion if you have:

- low blood volume (hypovolaemia) that is not adequately corrected by treatment with medicines.
- problems with a part of your nervous system called the 'autonomic nervous system'.
- narrowing of the main arteries in the neck (carotid artery). This means that not enough blood is getting to the brain (cerebrovascular insufficiency).
- or have ever had fits or convulsions.
- difficulty in breathing (bronchospasm).
- heart disease due to narrowing of your heart valves (stenotic valvular heart disease).

- inflammation of the membrane surrounding your heart (pericarditis) or a build-up of the fluid around your heart (pericardial effusion).
- a left-right shunt in your heart. This will mean blood goes directly from the left side of your heart to the right side.
- narrowing of the left main artery supplying blood to your heart (left main coronary stenosis).
- had a recent heart attack, severe heart failure or you have had a heart transplant in the last year
- 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')
- 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 Infusion.

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'.

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

Children and adolescents

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

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Adenosine Infusion can affect the way some other medicines work. Also some medicines can affect the way Adenosine Infusion 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 tell you to stop taking dipyridamole 24 hours before you are given Adenosine Infusion or you may be given a much lower dose of Adenosine Infusion.
- 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 may 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 such as 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 pregnant or breast-feeding.

Important information about some of the ingredients of Adenosine Infusion

This medicinal product contains approximately 36mg sodium per vial (10ml). This should 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 (this is called an intravenous infusion).
- Your heart rate and blood pressure will be closely monitored.

How much Adenosine Infusion is given

If you are not sure why you are being given Adenosine Infusion or have

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 SmPC 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.

Posology:

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).

any questions about how much Adenosine Infusion is being given to you, speak to your doctor or nurse.

Adults (including the elderly)

- The dose is calculated according to your weight.
- The usual dose is 140 micrograms per kilogram of bodyweight, per minute. This is given over a period of six minutes through an infusion pump (a slow injection into a vein).
- The dose of Adenosine Infusion is not changed if you have liver or kidney problems.

If you have more Adenosine Infusion than you should

As 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.

As 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. 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 or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Adenosine Infusion can cause side effects, although not everybody gets them.

While you are being given Adenosine Infusion you may have some of the following side effects:

If any of the following 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 (may affect more than 1 in 10 people)

- 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 (may affect up to 1 in 10 people)

- 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 (may affect up to 1 in 100 people)

- 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 (may affect up to 1 in 1,000 people)

- 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 (may affect up to 1 in 10,000 people)

- 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)

- Allergic reactions including swelling of the face or throat, and skin

reactions such as hives or rash

- 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 above 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.

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

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 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 discoloration 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 Malta please call UK +44 1978 661261

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)

Germany: Adenosin Altamedics 30mg/10ml Infusionslösung

Malta: Adenosine 30mg/10ml Solution for Infusion

This leaflet was last revised in 11/2018

105564/5

WOCKHARDT

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 discoloration 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

Malta: MA 154/10602

Date of Revision of Text: 11/2018

105564/5

WOCKHARDT