Package leaflet: Information for the user
Adenosine 30mg / 10ml solution for infusion

The name of your medicine is Adenosine 30 mg/10 ml solution for infusion, which will be referred to as Adenosine throughout this leaflet.

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.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Adenosine is and what it is used for
2. Before you are given Adenosine
3. How Adenosine is given
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1. What Adenosine is and what it is used for
Adenosine contains a medicine called adenosine. This belongs to a group of medicines called 'coronary vasodilatators'.
This medicine is for diagnostic use only.
Adenosine is used before a test called "myocardial perfusion imaging" to look at your heart. During this test you are given a medicine called a "radiopharmaceutical".
Adenosine 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 procedure is used if you are not capable of exercise or if an exercise stress test is not possible.

2. Before you are given Adenosine
Do not have this medicine and tell your doctor if:
- You are allergic (hypersensitive) to adenosine or any of the other ingredients of Adenosine (listed in section 6 below).
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have very low blood pressure (severe hypotension).
- You have unstable angina which is not controlled by treatment with medicine.
- You have asthma or any other severe breathing problem.
- You are taking a medicine called dipyridamole used to thin the blood.
- You have a type of heart failure where your heart is not pumping out enough blood.
- You have problems with your heart rhythm and do not have a pace maker (second or third degree AtrioVentricular block, sick sinus syndrome).
- 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.
  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 or nurse before you have Adenosine if:
- You have low blood volume (hypovolaemia) that is not adequately corrected by treatment with medicines.
- 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). This means that not enough blood is getting to the brain (cerebrovascular insufficiency).
- You have or have ever had fits or convulsions.
- You have difficulty in breathing (bronchospasm).
- You have heart disease due to narrowing of your heart valves (stenotic valvular heart disease).
- You have inflammation of the membrane surrounding your heart (pericarditis) or a build-up 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 an unusual heart rhythm. For example, your heartbeat is very fast or uneven (atrial fibrillation or atrial flutter) and in particular if you have an 'accessory conduction pathway'.
  You have any minor problem with your heart (first degree AtrioVentricular block or bundle branch block). These conditions may be temporarily aggravated when you are given Adenosine.
  If you are not sure if any of the above apply to you, talk to your doctor or nurse before being given Adenosine.

Other medicines and Adenosine
Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Adenosine can affect the way some other medicines work. Also some medicines can affect the way Adenosine 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 or you may be given a much lower dose of Adenosine.
- Aminophylline, theophylline or other xanthines (medicines used to help breathing). Your doctor may tell you to stop taking it 24 hours before you are given Adenosine.

Adenosine with food and drink
Food and drinks containing xanthines such as tea, coffee, chocolate and cola should be avoided for at least 12 hours before you are given Adenosine.

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 unless clearly necessary
- You are breast-feeding. You should not be given Adenosine.
  Ask you doctor or nurse for advise before taking any medicine if you are pregnant or breast-feeding.

If you are below 18 years of age
The use of Adenosine solution for infusion in children and adolescents has not been sufficiently studied.

Driving and using machines
Not relevant. There are no known effects on driving and using machines.

Adenosine contains sodium
Adenosine contains 35.42 mg sodium per infusion vial (10 ml). This should be taken into consideration by patients on a controlled sodium diet.

3. How Adenosine is given
How Adenosine is given
- Adenosine is a medicine for use in hospitals.
- It will be given to you by a doctor or nurse as an injection. The injection will be into one of your veins and be given over a period of time (this is called an intravenous infusion).
- Your heart and blood pressure will be closely monitored.

How much Adenosine is given
If you are not sure why you are being given Adenosine or have any questions about how much Adenosine 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 body weight, 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 is not changed if you have liver or kidney problems.

If you have more Adenosine than you should
As this medicine is given to you by a doctor or nurse it is unlikely that you will be given too much. Your doctor will carefully work out how much Adenosine 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

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The following information is intended for healthcare professionals only:

Posology and Method of Administration
Adenosine 30 mg/10 ml solution for 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 30 mg/10 ml solution for 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 30 mg/10 ml solution for 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 30 mg/10 ml solution for infusion and radionuclide administration are recommended to avoid an adenosine bolus effect.
2. After three minutes of Adenosine 30 mg/10 ml solution for 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 30 mg/10 ml solution for infusion.
3. To avoid an adenosine bolus effect, blood pressure should be measured in the arm opposite to the Adenosine 30 mg/10 ml solution for infusion.

The table below is given as a guide for adjustment of the infusion rate of undiluted Adenosine 30 mg/10 ml solution for 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 0-18 years old have not been established. Currently available data are described in section 5.1 but no recommendation on a posology can be made.

Elderly:
See dosage recommendations for adults.

Incompatibilities
Compatibility with other medicines is not known.
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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 can cause side effects, although not everybody gets them. While you are being given Adenosine 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 (affects more than 1 user in 10)
- Reddening of 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 1000)
- 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 (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)
- 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).
- Spasm of the artery in the heart which may lead to a heart attack

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.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report any 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

Keep this medicine out of the sight and reach of children

Adenosine should not be used after the expiry date which is stated on the carton and on the label. The expiry date refers to the last day of that month.

Shelf-Life

Unopened: 24 Months
Any portion of the vial not used at once should be discarded.

Special Precautions for Storage

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C. Do not refrigerate.

Nature and Contents of Container

Sulfur treated clear tubular Glass vial, Ph. Eur. Type-I with Teflon coated rubber closure and 10 ml fill volume.
Packs of 5, 6, 10 and 25 vials.
Not all pack sizes may be marketed.

Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirement.

Do not store above 25 °C. Do not refrigerate.
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 the solution contains particles or is discolored.

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 contains
- The active substance is adenosine.
  Each ml of solution for infusion contains 3 mg adenosine.
  Each 10 ml vial of contains 30 mg of adenosine.
- The other ingredients are sodium chloride and sterile water for injections.

What Adenosine looks like and contents of the pack

Adenosine is a clear and colourless to almost colourless solution, free from visible particle.
Each pack contains 5, 6, 10 and 25 vials.
Not all packs may be marketed.

Marketing Authorisation Holder

Baxter Healthcare Limited
Caxton Way
Thetford, Norfolk IP24 3SE
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Manufacturer

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7860 Lessines
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