

The following information is intended for healthcare professionals only:

Adenoscan® 30mg/10ml solution for infusion

sanofi

Practical information on preparation and handling of Adenoscan® 30mg/10ml Solution for Infusion (see also Section 3)

Posology and method of administration

Adenoscan 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 Adenoscan continuous electrocardiogram (ECG) control is necessary as life-threatening arrhythmia might occur. Heart rate and blood pressure should be monitored every minute.

Posology

Adults

1. Adenoscan should be administered undiluted as a continuous peripheral intravenous infusion at a dose of 140µg/kg/min for six minutes using an infusion pump. Separate venous sites for Adenoscan and radionuclide administration are recommended to avoid an adenosine bolus effect.

2. After three minutes of Adenoscan 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 Adenoscan infusion.
3. To avoid an adenosine bolus effect, blood pressure should be measured in the arm opposite to the Adenoscan infusion.

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

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Adenoscan® 30mg/10ml solution for infusion

Adenosine

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If this leaflet is hard to see or read? Phone 0800 035 2525 for help

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

What is in this leaflet:

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

1. What Adenoscan is and what it is used for



Adenoscan contains a medicine called adenosine. This belongs to a group of medicines called ‘coronary vasodilators’.

This medicine is for diagnostic use only.

Adenoscan 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”.

Adenoscan 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. What you need to know before you are given Adenoscan



Do not have this medicine and tell your doctor 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.
- ✗ 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 pacemaker (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 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 Adenoscan.



Warnings and precautions

Check with your doctor or nurse before you have Adenoscan 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 Adenoscan.

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 Adenoscan.

Children and adolescents

Adenoscan use in children and adolescents has not been sufficiently studied.



Other medicines and Adenoscan

Please tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Adenoscan can affect the way some other medicines work. Also, some medicines can affect the way Adenoscan 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 Adenoscan or you may be given a much lower dose of Adenoscan.
- 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 Adenoscan.

Adenoscan 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 Adenoscan.

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 Adenoscan unless clearly necessary.
- You are breast-feeding. You should not be given Adenoscan.

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.

Adenoscan contains sodium

This medicine contains 35.4mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.77% of the recommended maximum daily dietary intake of sodium for an adult.

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Paediatric population

The safety and efficacy of adenosine in children aged 0-18 years old have not been established.

Elderly

See dosage recommendations for adults.

Overdose

Overdosage would cause severe hypotension, bradycardia or asystole. The half-life of adenosine in blood is very short, and side effects of Adenoscan (when they occur) would quickly resolve when the infusion is discontinued. Administration of IV aminophylline or theophylline may be needed.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life

The shelf life of the unopened product is 3 years.

The medicinal product should be used immediately after opening.

Special precautions for storage

Do not refrigerate.

Special precautions for disposal and handling

The product is for single use only.

The product should be inspected visually for particulate matter and colouration prior to administration. Where the visual appearance of the product may have changed, the vial should be discarded.

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

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3. How Adenoscan is given

- Adenoscan 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 Adenoscan is given

If you are not sure why you are being given Adenoscan or have any questions about how much Adenoscan 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 Adenoscan is not changed if you have liver or kidney problems.

If you have more Adenoscan 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 Adenoscan 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 Adenoscan 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, Adenoscan can cause side effects, although not everybody gets them. While you are being given Adenoscan 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 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 1000 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 (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)
- 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.

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 MHRA Yellow Card Scheme at: 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 Adenoscan

This medicine will be kept by your doctor or nurse or pharmacist in a safe place where children cannot see or reach it.

Adenoscan 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.

Do not refrigerate.

The medicine 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.

Adenoscan should not be used if your doctor or nurse notice any particles in the solution or any discoloration 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. These measures will help protect the environment.

6. Contents of the pack and other information

What Adenoscan contains

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

What Adenoscan looks like and contents of the pack

Adenoscan is a clear, sterile, colourless solution for infusion.

Each pack contains 6 single use vials of 30mg/10ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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