

Package leaflet: Information for the user Adenosine 3mg / ml solution for injection Adenosine

The name of your medicine is Adenosine 3 mg/ml solution for injection, which will be referred to as Adenosine throughout this leaflet.

Read all of this leaflet carefully before you start taking 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. What you need to know before you take Adenosine
3. How to take Adenosine
4. Possible side effects
5. How to store Adenosine
6. Contents of the pack and other information

1. What Adenosine is and what it is used for

Adenosine contains the active ingredient called adenosine. This belongs to a group of medicines called 'antiarrhythmics'. Adenosine works by slowing down electrical impulses between the upper and lower chambers of the heart. This slows the fast or uneven heartbeats called 'arrhythmias'.

Adenosine is used:

- 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 'paroxysma supraventricular tachycardia (SVT)' or 'Wolff-Parkinson-White Syndrome'

In children, Adenosine bolus 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)

2. What you need to know before you take 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 asthma or any other severe breathing problem
- You have very low blood pressure (severe hypotension)
- 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, nurse or pharmacist before you have Adenosine.

Warnings and precautions

Talk to your doctor or nurse before taking Adenosine 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 been told that you have a heart problem whereby the electrical impulses in parts of your heart take longer than normal to discharge and then recharge (prolonged QT interval)
- 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 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 get a very slow heartbeat (severe bradycardia), respiratory failure, a heart problem that can be fatal (asystole), severe chest pains (angina) or very low blood pressure (severe hypotension),

then treatment with Adenosine should be stopped.

If you are below 18 years of age

In children with a heart rhythm trouble called 'Wolff-Parkinson-White (WPW) syndrome', Adenosine bolus may cause some unexpected severely abnormal heart rhythm.

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, nurse or pharmacist 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 Adenosine can affect the way some other medicines work. Also some medicines can affect the way Adenosine works.

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

Adenosine with food and drink

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.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

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

Adenosine contains sodium

Adenosine contains 3.542 mg sodium per ml (7.08 mg sodium per 2 ml vial). This should be taken into consideration by patients on a controlled sodium diet.

3. How to take Adenosine

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 into your vein
- Your heart and blood pressure will be closely monitored

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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, nurse or pharmacist.

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
- 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 bolus 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

If you take 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:

The following information is intended for healthcare professionals only:

Posology and Method of Administration

Adenosine 3 mg/ml 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 3 mg/ml 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.

Paediatric population

During administration of adenosine cardio-respiratory resuscitation equipment must be available for immediate use if necessary.

Adenosine is intended for use with continuous monitoring and ECG recording during administration.

The dosing recommended for the treatment of paroxysmal supraventricular tachycardia in the paediatric population is:

- first bolus of 0.1 mg/kg body weight (maximum dose of 6mg)
- increments of 0.1 mg/kg body weight as needed to achieve termination of supraventricular tachycardia (maximum dose of 12mg).

- 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 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, 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 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.

Very common (affects 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 (affects up to 1 in 10 people)

- Feeling dizzy or light-headed
- Feeling sick (nausea)
- Headache
- Unusual skin sensations such as burning
- Feeling nervous

Uncommon (affects 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)
- Feeling pressure in your head, or weighed down in your arms
- Feeling of general discomfort, weakness or pain
- Sweating

Very rare (affects 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
- Severe bradycardia (very slow heartbeat)

Other side effects

- Allergic reactions including swelling of the face or throat, and skin reactions such as hives or rash
- 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.

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.

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 discoloured.

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 injection contains 3 mg adenosine
Each 2ml vial contains 6mg of adenosine.

Method of administration

Adenosine should be administered by rapid intravenous (IV) bolus injection into a vein or into an IV line. If given into an IV line it should be injected through as proximally as possible, and followed by a rapid saline flush. If administered through a peripheral vein, a large bore cannula should be used.

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.

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.

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 2 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 requirements.

- The other ingredients are sodium chloride and 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
United Kingdom

Manufacturer

Bieffe Medital S.P.A.
Via Nuova Provinciale - 23034 Grosotto (SO),
Italy

UAB Norameda
Meistru 8a, Vilnius 02189,
Lithuania

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

Austria: Adenosin BAXTER 3 mg/ml Injektionslösung
Portugal: Adenosina Baxter 6mg/2ml solução injetável
Germany: ADENOSIN BAXTER 6 mg/2 ml Injektionslösung

This leaflet was last revised in month October 2021.