The following information is intended for medical or healthcare professionals only

ADENOSCAN® 30mg/10ml SOLUTION FOR INFUSION

SANOFI

1 NAME OF THE MEDICINAL PRODUCT
Adenoscan 30mg/10ml, solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 10ml vial of Adenoscan contains 30mg of adenosine (3mg/ml)
Excipient with known effect:
Each vial contains 90mg of sodium chloride (9mg/ml).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Solution for infusion.
Adenoscan is a sterile clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Intravenous (IV) Adenoscan 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.

4.2 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

Paediatric population
The safety and efficacy of adenosine in children aged 0-18 years 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.

4.3 Contraindications
Adenoscan is contra-indicated in patients suffering from:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Second or third degree AtrioVentricular (AV) block, sick sinus syndrome except in patients with a functioning artificial pacemaker.
- Long QT syndrome.
- Severe hypotension.
- Unstable angina not successfully stabilised with medical therapy.
- Decompensated states of heart failure.
- Chronic obstructive lung disease with evidence of bronchospasm (e.g. asthma bronchiale).
- Concomitant use of dipyridamole (see section 4.5).

4.4. Special warnings and precautions for use
Adenosine is intended for use in a hospital setting with monitoring and cardio-respiratory resuscitation equipment available for immediate use if necessary. During administration, continuous ECG monitoring is necessary as life-threatening arrhythmia might occur (see section 4.2).

Because it has the potential to cause significant hypotension, Adenoscan should be used with caution in patients with left main coronary stenosis, uncorrected hypovolemia, stenotic valvular heart disease, left to right shunt, pericarditis or pericardial effusion, autonomic dysfunction or stenotic carotid artery disease with cerebrovascular insufficiency. Adenoscan infusion should be discontinued in any patient who develops persistent or symptomatic hypotension. There have been reports of cerebrovascular accident/transient ischemic attack, secondary to the haemodynamic effects of adenosine.
There have been reports of myocardial infarction shortly after use of Adenoscan. Adenoscan should be used with caution in patients with recent myocardial infarction or severe heart failure. Adenoscan should be used with caution in patients with minor conduction defects (first degree AV block, bundle branch block) that could be transiently aggravated during infusion.
Adenosine may trigger convulsions in patients who are susceptible to convulsions.
Adenoscan should be used with caution in patients with atrial fibrillation or flutter and especially in those with an accessory by-pass tract since particularly the latter may develop increased conduction down the anomalous pathway.
Rare cases of severe bradycardia have been reported. Some occurred in early post-transplant patients; in the other cases occult sino-atrial disease was present. The occurrence of severe bradycardia should be taken as a warning of underlying disease and should lead to treatment discontinuation. Severe bradycardia would favour the occurrence of torsades de pointes, especially in patients with prolonged QT intervals. But to date, no case of torsades de pointes has been reported when adenosine is continuously infused.
The occurrence of respiratory failure (potentially fatal), asystole/cardiac arrest (potentially fatal), angina, severe bradycardia or severe hypotension should also lead to treatment discontinuation.
In patients with recent heart transplantation (less than 1 year) an increased sensitivity of the heart to adenosine has been observed.
Adenosine may precipitate or aggravate bronchospasm (see sections 4.3 and 4.8).
Adenoscan contains 9mg sodium chloride per ml (corresponding to 3.54mg sodium per ml).
To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction
Dipyridamole inhibits adenosine cellular uptake and metabolism, and potentiates the action of Adenoscan. In one study dipyridamole was shown to produce a 4-fold increase in adenosine actions. It is therefore suggested that Adenoscan should not be administered to patients receiving dipyridamole; if use of Adenoscan is essential, dipyridamole should be stopped 24 hours before hand, or the dose of Adenoscan should be greatly reduced.
Aminophylline, theophylline and other xanthines are competitive adenosine antagonists and should be avoided for 24 hours prior to use of Adenoscan.
Food and drinks containing xanthines (tea, coffee, chocolate and cola) should be avoided for at least 12 hours prior to use of Adenoscan.
Adenosine may interact with drugs tending to impair cardiac conduction.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of adenosine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Adenosine is not recommended during pregnancy unless the physician considers the benefits to outweigh the potential risks.

Breast-feeding
It is unknown whether adenosine metabolites are excreted in human milk. Adenoscan should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines
Not relevant.

4.8 Undesirable effects
Effects related to the known pharmacology of adenosine are frequent, but usually self-limiting and of short duration. Discontinuation of infusion may be necessary if the effect is intolerable.
Methylxanthines, such as IV aminophylline or theophylline have been used to terminate persistent side effects (50-125mg by slow intravenous injection).
Adverse events are ranked under the heading of the frequency:
Very common (>1/10), Common (≥1/100, <1/10), Uncommon (≥1/1000, <1/100), Rare (≥1/10000, <1/1000), Very rare (<1/10000), Not known (cannot be estimated from available data).

Immune system disorders:
- Not known: anaphylactic reaction (including angioedema and skin reactions such as urticaria and rash)

Cardiac disorders:
- Common: ST segment depression, sustained or non-sustained ventricular tachycardia, AV block (see section 4.4).

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PACKAGE LEAFLET:
INFORMATION FOR THE USER

Adenoscan® 30 mg/10 ml solution for infusion

Adenosine

SANOFI

If this leaflet is hard to see or read Phone 0845 372 7101 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

Adenoscan contains a medicine called adenosine. This belongs to a group of medicines called 'coronary vasodilatators'.

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 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 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 nervoussystem 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.

Ask you doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding.

Adenoscan contains sodium (34.5mg per infusion vial (10ml)). You may receive up to 0.99mg of sodium per kilogram of body weight. This should be taken into consideration by patients on a controlled sodium diet.

3. How Adenoscan is given

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.

Turn Over

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If sustained second or third degree AV block develops the infusion should be discontinued. If first degree AV block occurs, the patient should be observed carefully as a quarter of patients will progress to a higher degree of block.
- Uncommon: bradycardia sometimes severe (see section 4.4)
- Not known: asystole /Cardiac arrest (sometimes fatal, especially in patients with underlying ischemic heart disease/cardiac disorders, see section 4.4), sinus tachycardia, atrial fibrillation, ventricular fibrillation

Nervous system disorders:
- Very common: headache
- Common: dizziness, light-headedness, paraesthesia
- Rare: tremor, drowsiness
- Not known: loss of consciousness / syncope, convulsions, especially in predisposed patients (see section 4.4)

Eye disorders:
- Rare: blurred vision

Ear and labyrinth disorders:
- Rare: tinnitus

Respiratory, thoracic and mediastinal disorders:
- Very common: dyspnoea (or the urge to breathe deeply)
- Rare: bronchospasm (see section 4.4), nasal congestion
- Very rare: respiratory failure (see section 4.4)
- Not known: apnoea/respiratory arrest

Cases with fatal outcome of respiratory failure, of bronchospasm, and of apnoea / respiratory arrest have been reported.

Gastro-intestinal disorders:
- Very common: abdominal discomfort
- Common: dry mouth
- Uncommon: metallic taste
- Not known: nausea, vomiting

Renal and Urinary disorders:
- Rare: urinary urgency

Vascular disorders:
- Very common: flushing
- Common: hypotension, sometimes severe (see section 4.4)

General disorders and administration site conditions:
- Very common: chest pain or pressure, feeling of thoracic constriction/oppression
- Common: throat, neck and jaw discomfort
- Uncommon: sweating, discomfort in the leg, arm or back, feeling of general discomfort, weakness/pain
- Very rare: injection site reactions

Reproductive system and breast disorders:
- Rare: nipple discomfort

Psychiatric disorders:
- Uncommon: nervousness

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the MHRA Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other Cardiac Preparations ATC Code: C01EB10
Endogenous nucleoside with peripheral vasodilator/antiarrhythmic effect
Adenosine is a potent vasodilator in most vascular beds, except in renal afferent arterioles and hepatic veins where it produces vasoconstriction. Adenosine exerts its pharmacological effects through activation of purine receptors (cell-surface A1 and A2 adenosine receptors). Although the exact mechanism by which adenosine receptor activation relaxes vascular smooth muscle is not known, there is evidence to support both inhibition of the slow inward calcium current reducing calcium uptake, and activation of adenylate cyclase through A2 receptors in smooth muscle cells. Adenosine may reduce vascular tone by modulating sympathetic neurotransmission. The intracellular uptake of adenosine is mediated by a specific transmembrane nucleoside transport system. Once inside the cell, adenosine is rapidly phosphorylated by adenosine kinase to adenosine monophosphate, or deaminated by adenosine deaminase to inosine. These intracellular metabolites of adenosine are not vasoactive. Intracoronary Doppler flow catheter studies have demonstrated that intravenous Adenoscan at 140µ g/kg/min produces maximum coronary hyperaemia (relative to intracoronary papaverine) in approximately 90 % of cases within 2-3 minutes of the onset of the infusion.
Coronary blood flow velocity returns to basal levels within 1-2 minutes of discontinuing the Adenoscan infusion.
The increase in blood flow caused by Adenoscan in normal coronary arteries is significantly more than that in stenotic arteries. Adenoscan redirects coronary blood flow from the endocardium to the epicardium and may reduce collateral coronary blood flow thereby inducing regional ischaemia.
Continuous infusion of adenosine in man has been shown to produce a mild dose-dependent fall in mean arterial pressure and a dose-related positive chronotropic effect, most likely caused by sympathetic stimulation. The onset of this reflex increase in heart rate occurs later than the negative chronotropic/dromotropic effect. This differential effect is mostly observed after bolus injection thus explaining the potential use of adenosine as a treatment for supraventricular arrhythmias when administered as a bolus or as a coronary vasodilator when administered as an infusion.
Although Adenoscan affects cardiac conduction, it has been safely and effectively administered in the presence of other cardioactive or vasoactive drugs such as beta adrenergic blocking agents, calcium channel antagonists, nitrates, ACE inhibitors, diuretics, digitalis or anti-arrhythmics.

Paediatric population
Literature review identified three studies where intravenous adenosine infusion was used in conjunction with radionuclide myocardial perfusion imaging at a dose of 0.14mg/kg body weight/min for 2-4 minutes in paediatric patients aged 1 month to 18 years. The largest study included 47 patients aged 1 month to 18 years of age and reported 87% sensitivity (CI 52-97%) and 95% specificity (CI 79-99%) for cardiovascular magnetic resonance imaging under pharmacological stress with intravenous adenosine in a dose of 0.14mg/kg/min for 3 minutes. No adverse events were reported in the study. However, the currently available data is considered very limited to support the use of adenosine for diagnostic purposes in the paediatric population.

5.2 Pharmacokinetic properties
It is impossible to study adenosine in classical pharmacokinetic studies. It is present in various forms in all the cells of the body where it plays an important role in energy production and utilisation systems. An efficient salvage and recycling system exists in the body, primarily in erythrocytes and blood vessel endothelial cells. The half-life in vitro is estimated to be less than 10 seconds.
The in vivo half-life may be even shorter.
Since neither the kidney nor the liver are involved in the degradation of exogenous adenosine, the efficacy of Adenoscan should be unaffected by hepatic or renal insufficiency.

5.3 Preclinical safety data
Because adenosine is naturally present in all living cells, studies in animals to evaluate the carcinogenic potential of Adenoscan (adenosine) have not been performed.
No controlled reproductive studies were conducted in animals with adenosine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium Chloride
Water for Injection

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

6.3 Shelf life
The shelf life of the unopened product is 3 years.
The medicinal product should be used immediately after opening.

6.4 Special precautions for storage
Do not refrigerate (see section 6.3).

6.5 Nature and contents of container
Type I glass vials with chlorobutyl rubber stoppers, packs with 6 vials.

6.6 Special precautions for disposal and handling
See section 4.2.
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 product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER
Sanofi
One Onslow Street
Guildford
GU1 4YS
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 04425/0682

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
26 September 2005

10 DATE OF REVISION OF THE TEXT
July 2018

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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 eects 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)

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: 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 discolouration 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:
Sanofi
One Onslow Street
Guildford
GU1 4YS
UK
Tel: 0845 372 7101
e-mail: uk-medicalinformation@sanofi.com

Manufacturer:
FAMAR HEALTH CARE SERVICES MADRID, S.A.U.
Avda. Leganés, 62, Alcorcón 28923 (Madrid) Spain

This leaflet was last approved in August 2018

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FAMAR HEALTH CARE SERVICES MADRID, S.A.U.

Artworks Department. Madrid. Spain

COLOURS

Product Description: **Adenoscan 30mg / 10ml 6 vial.**

P. Reflex blue

SAP-/ID number:	11502820-06	Technical drawing St:	646
Replace:	11502820-05	Zt:	646-1
Version number:	04	Dimensions:	157x630
Date:	29.08.2018	Laetus number:	810
Country:	UK	Folder nº:	3737957
Designer:	Ana Arteaga	Minimum point size:	8