Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Adenoscan?

Adenoscan contains the active ingredient adenosine. Adenoscan is used as an aid to doctors, to understand how your heart is working. Adenoscan is used during radionuclide imaging of your heart.

For more information, see Section 1. Why am I using Adenoscan? in the full CMI.

2. What should I know before I use Adenoscan?

Do not use if you have ever had an allergic reaction to Adenoscan or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Adenoscan? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Adenoscan and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Adenoscan?

- Adenoscan will only be given to you in hospital.
- Adenoscan will be given to you as an injection.

More instructions can be found in Section <u>4. How do I use Adenoscan?</u> in the full CMI.

5. What should I know while using Adenoscan?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you have been given Adenoscan.
Things you should not do	• Do not eat or drink food or drinks containing caffeine (e.g. coffee, tea, chocolate or cola) for at least 12 hours before you receive your injection.
Looking after your medicine	 Adenoscan is stored in the pharmacy or on the ward. Adenoscan is kept in a cool, dry place where the temperature stays below 25°C. Not to be refrigerated.

For more information, see Section 5. What should I know while using Adenoscan? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Active ingredient: adenosine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Adenoscan. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Adenoscan.

Where to find information in this leaflet:

- 1. Why am I using Adenoscan?
- 2. What should I know before I use Adenoscan?
- 3. What if I am taking other medicines?
- 4. How do I use Adenoscan?
- 5. What should I know while using Adenoscan?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Adenoscan?

Adenoscan contains the active ingredient adenosine.

Adenoscan is used as an aid to doctors, to understand how your heart is working. Adenoscan is used during radionuclide imaging if your heart.

Adenoscan is given to you before the radionuclide (the agent which allows them to see your heart).

Adenoscan works by opening up your heart's blood vessels to allow blood to flow more freely and can then be seen more clearly by doctors.

Adenoscan is only given in hospitals. It is given to you as an injection.

Your doctor, however, may prescribe Adenoscan for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

This medicine is not addictive.

2. What should I know before I use Adenoscan?

Warnings

Do not receive Adenoscan if you:

- are allergic to it or any of the ingredients listed at the end of this leaflet.
- have asthma or any other lung disease
- have recently had a heart transplant
- have some other problems with your heart or heart rhythm
- have severe low blood pressure

Tell your doctor if:

- you have allergies to any of the ingredients listed at the end of this leaflet
- you have allergies to any other medicines including:
- theophylline or aminophylline
- dipyridamole
- carbamazepine

• you have allergies to any other substance, such as foods, preservatives or dyes

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Tell your doctor if you eat or drink large amounts of food or drinks containing caffeine (e.g. coffee, tea, chocolate or cola).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Tell your doctor if you have or have had any medical conditions, especially the following:

- a history of heart problems including problems with your blood pressure
- a history of epilepsy or seizures
- asthma or any other lung disease

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Adenoscan is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of being given it if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether Adenoscan passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of being given it if you are breastfeeding or planning to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Adenoscan. These include:

- theophylline or aminophylline, medicines used to help relieve breathing problems
- dipyridamole, a medicine used for people who have had a stroke
- carbamazepine, a medicine used to treat epilepsy and seizures

These medicines may be affected by Adenoscan, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given Adenoscan.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Adenoscan.

4. How do I use Adenoscan?

How much is given

- The dosage of Adenoscan is calculated according to your weight. The recommended dose in adults is 140 micrograms/kg/min given for six minutes (total dose will be 0.84 mg/kg).
- After three minutes of the Adenoscan infusion you will be given the required dose of the radionuclide (imaging agent). This will also be given to you by injection.

How it is given

- Adenoscan will only be given to you in hospital.
- Adenoscan will be given to you as an injection.

When to receive it

 Do not eat or drink food or drinks containing caffeine (e.g. coffee, tea, chocolate or cola) for at least 12 hours before you receive your injection.

If you receive too much

As Adenoscan is given to you under the supervision of a doctor, it is very unlikely that you will receive too much.

However, if you experience any unexpected or worrying side effects after being given Adenoscan and think you have been given too much, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

5. What should I know while using Adenoscan?

Things you should not do

 Do not eat or drink food or drinks containing caffeine (e.g. coffee, tea, chocolate or cola) for at least 12 hours before you receive your injection.

After being given Adenoscan

 If you have any queries about any aspects of your medicine, or any questions regarding this leaflet, discuss them with your doctor, nurse or pharmacist.

Looking after your medicine

- Adenoscan is stored in the pharmacy or on the ward.
- Adenoscan is kept in a cool, dry place where the temperature stays below 25°C.
- Not to be refrigerated.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Adenoscan.

It helps most people with heart problems, but it may have unwanted side effects in a few people.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 facial flushing shortness of breath a feeling of tightness across the chest nausea or stomach pain a dry mouth a tingling sensation in your arrow or legs headache dizziness and lightheadedness discomfort in the throat, neck jaw a burning sensation 	these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 irregular or slow heartbeat problems with your breathing spasm of the artery in the heart which may lead to a heart attack 	Tell your doctor or nurse immediately.
 Swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing Rash, itching or hives on the skin 	Stop receiving this medicine and tell your doctor immediately.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/</u> <u>reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Adenoscan contains

Active ingredient (main ingredient)	adenosine 30 mg
Other ingredients	sodium chloride
	sterile water

(inactive ingredients)	
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What Adenoscan looks like

Adenoscan is a clear colourless solution that comes in a glass vial.

Each box of Adenoscan contains 6 vials.

AUST R 53226.

Who distributes Adenoscan

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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