Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 Adenocor?

Adenocor contains the active ingredient adenosine. Adenocor is used as an aid to doctors, to understand how your heart is working. Adenocor is a type of medicine used to treat a condition where the heart beats too rapidly.

For more information, see Section <u>1. Why am I using Adenocor?</u> in the full CMI.

2. What should I know before I use Adenocor?

Do not use if you have ever had an allergic reaction to Adenocor 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 Adenocor? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Adenocor 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 Adenocor?

- Adenocor will only be given to you in hospital.
- Adenocor will be given to you as a rapid injection over a couple of seconds.

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

5. What should I know while using Adenocor?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have been given Adenocor.
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	 Adenocor is stored in the pharmacy or on the ward. Adenocor is kept in a cool, dry place where the temperature stays below 25°C. Not to be refrigerated.

For more information, see Section <u>5. What should I know while using Adenocor?</u> 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 Adenocor. 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 Adenocor.

Where to find information in this leaflet:

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

1. Why am I using Adenocor?

Adenocor contains the active ingredient adenosine.

Adenocor is a type of medicine used to treat a condition called paroxysmal supraventricular tachycardia (including a condition called Wolff-Parkinson-White syndrome). This is when the heart beats too rapidly. If left untreated this condition can be life threatening.

Adenocor is used as an aid to doctors, to understand how your heart is working.

Adenocor works by slowing down the electrical impulses which control the heart rhythm. This allows the heart rhythm to return to normal.

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

The effect of Adenocor only lasts for a couple of minutes.

Your doctor, however, may prescribe Adenocor 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 Adenocor?

Warnings

Do not receive Adenocor 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, Adenocor 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 Adenocor 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 Adenocor. 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 Adenocor 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 Adenocor.

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

4. How do I use Adenocor?

How much is given

- The standard dose for this medicine is a series of injections
- Adults: One injection (3 mg). If the first injection does not slow down your heart rate within 1 or 2 minutes, one (6 mg) or two (12 mg) more doses may be given
- Children: There is not enough evidence to recommend the use of this medicine for children

How it is given

- Adenocor will only be given to you in hospital.
- Adenocor will be given to you as a rapid injection over a couple of seconds

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 Adenocor 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 Adenocor and think you have been given too much, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

5. What should I know while using Adenocor?

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 Adenocor

 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

- Adenocor is stored in the pharmacy or on the ward.
- Adenocor 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 Adenocor.

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 headache dizziness and lightheadedness discomfort in the throat, neck or jaw a burning sensation 	Speak to your doctor if you have any of 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/reporting-problems</u> in Australia or in New Zealand at

<u>https://pophealth.my.site.com/carmreportnz/s/</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 Adenocor contains

Active ingredient	adenosine 6 mg
(main ingredient)	
Other ingredients	sodium chloride
(inactive ingredients)	sterile water
Potential allergens	N/A

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

What Adenocor looks like

Adenocor is a clear colourless solution that comes in a glass vial with a rubber closure and aluminium cap.

Each box of Adenocor contains 6 vials.

AUST R 49439.

Who distributes Adenocor

Distributed in Australia by: sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113 Freecall: 1800 818 806 Email: <u>medinfo.australia@sanofi.com</u>

Distributed in New Zealand by: Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics P O Box 62027 Sylvia Park Auckland 1644 Freecall: 0800 283 684 Email: <u>medinfo.australia@sanofi.com</u>

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