Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cardasa.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Cardasa against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Cardasa is used for

Cardasa is an enteric coated low dose aspirin (100 mg) tablet.

Low dose aspirin helps reduce blood stickiness, the tendency of blood to clot. Cardasa may be useful if you are at risk of angina, transient ischaemic attacks (TIAs or ministrokes), stroke (due to a blood clot) or heart attacks if you already have heart or blood vessel disease.

The amount of aspirin in Cardasa is much less than you would need to take for a headache or other pain. If you require medication for temporary relief of these symptoms, we suggest you take (paracetamol).

Cardasa is for use under medical supervision only.

Use in children

Cardasa is not recommended for use in children under 18 years of age. Consult a doctor before giving this medication to children or teenagers with chickenpox, influenza or fever.

Before you take Cardasa

When you must not take it Do not take Cardasa if you have an allergy to:

 non-steroidal anti-inflammatory drugs, aspirin or any of the other ingredients contained in this medicine. The ingredients are listed at the end of this leaflet.

Signs of an allergic reaction may include:

- · shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

If you have taken aspirin before and became unwell, tell your doctor or pharmacist before taking the first dose.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Cardasa passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should use Cardasa, talk to your doctor or pharmacist. Do not give this medicine to anyone else.

Before you take Cardasa

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- You have bronchial asthma
- You have bleeding tendencies or take anticoagulant therapy (medicine which thins blood e.g warfarin)
- You have bleeding or clotting disorders such as haemophilia, Von Willebrand's disease or hypothrombinaemia
- You have stomach bleeding or a history or stomach bleeding after treatment with aspirin or nonsteroidal anti-inflammatory drugs.
- You have any kidney or liver problems such as severe kidney or liver failure
- Gastritis or an active or previous stomach ulcer
- History of gout

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Cardasa.

Taking other medicines with Cardasa

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

Some medicines and Cardasa may interfere with each other. These include medicines which:

- Thin the blood (e.g. warfarin)
- Control arthritis or joint pain (e.g. NSAIDs)
- Treat gout (e.g. probenecid)
- Reduce inflammation (e.g. prednisolone)
- Control blood pressure
- Control diabetes
- Contain other salicylates or aspirin
- Contain methotrexate, chlorpropamide, sulphinpyrazone or spironolactone
- Contain corticosteroids

These medicines may be affected by Cardasa or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist will be able to tell you what to do when taking Cardasa with other medicines.

If you have not told the doctor or pharmacist about any of these things, tell him/her before you use Cardasa.

How to take Cardasa

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Do not take more than the recommended dose.

The recommended dosage is one Cardasa tablet at the same time every day. Take your first tablet from the appropriately marked day, then follow the days consecutively.

If you have any concerns about how to use Cardasa, talk to the doctor or pharmacist.

How to take Cardasa

Take Cardasa with a glass of water. Cardasa should be swallowed whole, without crushing, chewing or breaking the tablet.

Cardasa can be taken with or without food. Food does not alter the effects of Cardasa.

Take Cardasa at the same time each day. This will help you to remember when to take your medicine.

If you forget to take it

If you forget a dose of Cardasa, take it as soon as you remember.

However, if the next dose is due within 12 hours, skip the missed dose. Take the next dose at the normal time.

Do not take a double dose to make up for the dose that has been missed.

Using more than the prescribed dose can increase the chance of unwanted side effects.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Cardasa. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Be sure to show the doctor the Cardasa pack.

If you have any concerns about this, talk to your doctor or pharmacist.

While you are taking Cardasa

Things you must do

You must swallow Cardasa tablets whole.

Cardasa has an enteric coating that prevents the aspirin from being released in your stomach. This reduces the chance of the aspirin upsetting your stomach. The aspirin is released lower down, in the intestines, where it is absorbed gradually in to the blood stream.

Things to be careful of

It is advisable to withdraw aspirin at least one week before surgery.

Blood donors should cease all forms of aspirin at least a week before giving blood. Aspirin prolongs the time for blood to clot.

Be careful driving or operating machinery until you know how Cardasa affects you.

Cardasa may cause dizziness or light-headedness in some people. Make sure you know how you react to Cardasa before you drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after taking Cardasa.

Besides their main effect, medicines may have some unwanted effects. Unwanted effects do not always occur in every person. Most unwanted effects following Cardasa are mild, and may disappear without stopping Cardasa. However, some side effects may need medical treatment.

Tell the doctor or pharmacist about any effect which is troublesome or ongoing.

Events reported during treatment or following Cardasa which may have been related to the medicine are listed below.

Mild Events

Tell your doctor or pharmacist if you notice any of the following that are troublesome or ongoing:

- Heartburn
- Nausea

More serious events

Tell your doctor or pharmacist immediately if you notice any of the following:

- Increased bleeding (e.g. bruising easily, nose bleeds)
- · Itching or rashes

As with other medicines there is a very small risk of serious allergic reaction.

Contact your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following:

- Swelling of limbs, face, eyes, inside of nose, mouth or throat
- Shortness of breath, breathing or swallowing difficulties
- Hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
- Unusual tiredness or weakness that is sudden and severe

Other signs of allergy to aspirin may include:

- Asthma, rhinitis
- Swelling with fluid in tissues
- Redness, itchy rashes or pustular eruptions

Other rare events that have been reported with aspirin include:

- Increased or decreased excretion of uric acid
- Dizziness, tinnitus, vertigo and deafness
- Stomach ulceration

In the doses of aspirin administered in Cardasa the risk of these adverse events appears to be small.

You should tell the doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with Cardasa.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Cardasa

Storage

Keep the medication in the pack until it is time to use it.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicine.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that are left over.

Product description

What it looks like

Cardasa is a white to off-white colour circular, biconvex coated tablet, with a heart shape embossed on one side and plain on other side.

Cardasa is available in calendar packs of 28, 84 and 168 tablets.

Ingredients

The active ingredient in Cardasa is acetylsalicylic acid (aspirin) 100 mg.

Other inactive ingredients in Cardasa are:

- · Citric acid anhydrous
- Stearic acid
- Carbomer 941
- Betadex
- Methacrylic acid copolymer
- · Purified talc
- Pregelatinised maize starch
- Hypromellose
- Maize starch
- Sodium hydroxide
- Microcrystalline cellulose
- Macrogol 6000
- Titanium dioxide

This medicine does not contain lactose, tartrazine and azo dyes.

Supplier

Cardasa is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739) Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Phone: (02) 9298 3999 www.alphapharm.com.au

Australian registration numbers:

 Cardasa low dose aspirin 100 mg enteric coated tablet blister pack: AUST R 201525

This leaflet was prepared on 20 March 2013.