

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

CARDASA 100 mg tablets is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CARDASA 100 mg tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CARDASA 100 mg tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve while taking CARDASA 100 mg tablets.

What is in this leaflet

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2. What you need to know before you take CARDASA 100 mg tablets
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1. What CARDASA 100 mg tablets is and what it is used for

CARDASA 100 mg tablets contains the active ingredient acetylsalicylic acid (ASA), which acts against the clotting of platelets in the blood even at relatively low doses and can thus reduce the occurrence of blood clots.

By administration as gastro-resistant film-coated tablets, the side effects of acetylsalicylic acid on the stomach are reduced.

CARDASA 100 mg tablets gastro-resistant tablets are used

- For reducing the risk of myocardial infarction (heart attack) in patients with unstable angina pectoris (unexpected chest pains).

- For reducing the risk of further coronary occlusion after myocardial infarction (heart attack).
- To reduce the risk of blood clots, which may cause the occlusion of blood vessels in the heart after a heart operation (aortocoronary by-pass surgery).
- For reducing the risk for cardiovascular events (events concerning the heart or the vascular system) such as angina pectoris or myocardial infarction in patients with diabetes at high cardiovascular risk.
- CARDASA 100 mg tablets prevents blood clots from forming.

2. What you need to know before you take CARDASA 100 mg tablets

Do not take CARDASA 100 mg tablets

- If you are allergic to acetylsalicylic acid, other salicylates or any of the other ingredients of this medicine (listed in section 6).
- If you have ever reacted with hypersensitivity (allergy, asthma attacks) to certain medicines against pain, for example acetylsalicylic acid (ASA) at higher doses, or non-steroidal anti-inflammatory drugs (NSAIDs).
- If you have ever had an ulcer or bleeding problem (including perforation) in your stomach or small intestine which was caused by treatment with a non-steroidal anti-inflammatory drug (NSAID) against pain, fever or inflammation.
- If you currently have or have ever had an ulcer or bleeding/perforation in your stomach or small intestine.
- If you ever had the problem of your blood not clotting properly, for instance because you suffer from bleeding tendency or haemophilia (an inherited disorder of the blood) or have a reduced number of platelets in your blood (thrombocytopenia).
- If you have severe liver problems.
- If you have severe kidney problems.
- If you have severe heart problems (heart failure).
- If you have to take 15 mg per week or more of methotrexate (a medicine for the treatment of certain types of cancer or rheumatic disease).
- If you are taking medicines against blood clotting (oral anti-coagulants, so-called 'blood thinners') or ASA at high doses.

- During the last 3 months of pregnancy (see also section 2 Pregnancy, breastfeeding and fertility).
- If you suffer from oxaluria (a condition frequently causing formation of renal stones).

Warnings and precautions

Talk to your doctor or pharmacist before taking CARDASA 100 mg tablets:

- If you are hypersensitive to other medicines against pain (analgesics, anti-inflammatory medicines or medicines used to treat rheumatic disorders), or if you suffer from other allergies.
- If you have a history of high blood pressure or heart failure. In association with high-dose acetylsalicylic acid treatment, there have been reports of fluid retention in body tissue and swelling (oedema).
- If you are concomitantly treated with medicines against blood clots (anticoagulants).
- If you have or have ever had gastrointestinal ulcers, including chronic or repeatedly recurring ulcers, or gastrointestinal bleeding.
- If your liver function is impaired.
- Before surgical procedures (even smaller procedures such as tooth extraction). The risk of bleeding may increase. Please tell your doctor or dentist that you are taking CARDASA 100 mg tablets.
- If you are planning to take ibuprofen (a medicine against pain), as it may weaken the effect of CARDASA 100 mg tablets. You should talk to your doctor before taking CARDASA 100 mg tablets.
- If your kidney function or your cardiovascular system is impaired (problems of the vessels in your kidneys, heart failure, deficiency in the amount of blood in the body, major operations, sepsis (pus in the blood or tissue), or serious bleeding events), as ASA may increase the risk of an impairment of kidney function and acute kidney failure.

Please also talk to your doctor or pharmacist before taking CARDASA 100 mg tablets:

- If you are pregnant, think you are pregnant or are planning to have a baby.
- If you are breastfeeding.
- If you are taking other medicines additionally, particularly medicines containing ASA or medicines against pain or rheumatism.
- If you also suffer from other diseases or allergies.

Hypersensitivity/allergic reactions

CARDASA 100 mg tablets may induce bronchial spasms, asthma attacks or other hypersensitivity

reactions of the respiratory tract. The risk for these reactions is increased if you are asthmatic, have hay fever, nasal polyps or chronic respiratory diseases. The same applies to patients with allergies to other substances (for instance with skin reactions, itching, or hives).

Gastrointestinal problems

Severe – even life-threatening – bleeding, ulcers and/or perforation may occur at any time during treatment, also if you have not had any complaints or problems in the digestive tract before. You should therefore carefully watch out for any symptoms or complaints in your stomach or intestines while taking CARDASA 100 mg tablets.

The risk increases with higher doses, in elderly persons, those with a history of gastric ulcers (particularly if they were complicated by bleeding or perforation), and in patients concomitantly treated with other medicines which may increase the risk for ulcers or bleeding, for instance corticosteroids, blood-thinners, certain medicines against depression (selective serotonin re-uptake inhibitors – SSRIs) or other medicines against platelet aggregation.

If any of the above applies to you, your doctor may consider it necessary to reduce your dose of CARDASA 100 mg tablets and prescribe an additional medicine to protect your stomach. Please report any unusual symptom in your digestive tract (particularly signs of bleeding) to your doctor immediately, especially in the early stages of treatment.

If you experience bleeding or ulcers in the stomach or intestines, treatment with CARDASA 100 mg tablets must be stopped immediately.

Possible symptoms and signs of gastrointestinal complications

Pain in your stomach, vomiting blood, vomiting that looks like coffee grounds, black stools.

If any of these occur, stop taking CARDASA 100 mg tablets right away and contact a doctor immediately.

Bleeding tendency

ASA inhibits the clotting of blood cells (platelets) even at relatively low doses. This causes an increased bleeding risk during and after operations (including minor surgery such as tooth extractions), which may continue for several days after stopping to take the medicine.

In rare to very rare cases severe bleeding, for example in the brain, has been reported, particularly in patients with uncontrolled high blood pressure and/or concomitant treatment with other medicines preventing the clotting of blood. In exceptional cases, these bleeding events may be life-threatening.

Gout attack

CARDASA 100 mg tablets reduces uric acid excretion and can thus increase the level of uric acid in the blood. This may trigger gout attacks in predisposed patients.

Kidney damage

If ASA is taken over prolonged periods at high doses (against pain), this may lead to lasting kidney damage (nephropathy), which can progress to renal failure. This risk is especially high if you take over-the-counter pain medication in addition to the treatment prescribed by your doctor.

Laboratory tests

If you have to take CARDASA 100 mg tablets for a prolonged period, your doctor will ask you to have certain blood tests done (for instance liver function, kidney function, blood count, coagulation).

Glucose-6-phosphate dehydrogenase deficiency

In some people with so-called glucose-6-phosphate dehydrogenase deficiency (a metabolic disease), high doses of ASA could cause decay of red blood cells. If a patient with glucose-6-phosphate dehydrogenase deficiency needs to take CARDASA 100 mg tablets, this has to be done under strict medical supervision.

Fertility

CARDASA may affect fertility in women (see section 2 Pregnancy, breastfeeding and fertility).

Children and adolescents

In very rare cases so-called Reye's syndrome (a severe, life-threatening disease affecting the brain and the liver) has been reported in children and adolescents during treatment with acetylsalicylic acid, especially when it was used for treating fever or chicken pox. There may be a relationship with ASA, and the syndrome can also occur in young adults.

Medicines containing acetylsalicylic acid such as CARDASA 100 mg tablets should therefore be administered to children younger than 12 years and adolescents only if specifically prescribed by a doctor and only if other treatments have not proved effective. If continued vomiting, impaired consciousness and/or abnormal behaviour occurs (possibly after temporary improvement of the patient's general state), treatment with CARDASA 100 mg tablets must be stopped immediately and you must seek medical assistance.

As a precaution it is recommended that CARDASA 100 mg tablets should not be taken for at least 6

weeks following a vaccination against chicken pox.

Other medicines and CARDASA 100 mg tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment may be influenced if ASA is concomitantly taken with certain other medicines (see list of medicines and groups of medicines below).

If you take methotrexate (a medicine for the treatment of certain types of cancer or rheumatic diseases) *at a dosage of 15 mg per week or more*, you must avoid taking CARDASA 100 mg tablets.

If you are taking medicines reducing the clotting of blood (oral anticoagulants, sometimes also called blood thinners), you should not take ASA at higher doses.

Combinations requiring special caution:

- Methotrexate (a medicine for the treatment of certain types of cancer or rheumatic disorders) *at doses of 15 mg per week or less*: There is a risk of increased (side) effects of methotrexate.
- Medicines inhibiting the clotting of blood (anticoagulants) or dissolving blood clots, or other medicines preventing clotting of platelets (platelet aggregation inhibitors) or acting against the stopping of blood flow (so called haemostasis inhibitors). The increase in effect may induce or enhance bleeding.
- CARDASA 100 mg tablets may increase the bleeding risk if it is used before a treatment against blood clots (e.g. with warfarin). In case of such a treatment, you need to carefully watch for any symptoms or signs of outer or inner bleeding (e.g. bruises), and the therapy must be closely monitored by a doctor.
- Medicines taken against rejection of organ after transplantation (cyclosporine, tacrolimus).
- Other non-steroidal anti-inflammatory/anti-rheumatic medicines with ASA at high doses (more than 3 000 mg per day): Increased risk of ulcers and bleeding in the stomach or intestines, possibility of overdose.
- Certain medicines for depression (selective serotonin reuptake inhibitors – SSRIs): Increased risk of bleeding in the stomach.
- Digoxin, a cardiac glycoside (a medicine for treating heart failure and regulating the heartbeat): The effect may increase, and side effects may occur. Adequate monitoring and, where appropriate, dose adjustment by your doctor is recommended.
- Certain medicines for gout (e.g. benzbromarone, probenecid): Possibly decreased effect of the gout

medicines.

- Medicines to treat diabetes (e.g. insulin, sulphonylureas) used with ASA at high doses: Increase in effect which may cause hypoglycaemia (too low sugar levels in the blood). Patients should frequently check their glucose level.
- Certain medicines against high blood pressure (diuretics, 'water tablets'): There is a risk of severe kidney problems if taken with ASA at high doses (more than 3 000 mg per day). If this combination is used, patients should be careful to drink sufficient amounts of fluid. With certain diuretics (e.g. furosemide) the blood pressure lowering effect may be reduced; blood pressure should be monitored.
- Medicinal products containing cortisone or cortisone-like substances (except for products applied locally to the skin, and hydrocortisone used for cortisol replacement therapy in Addison's disease): Increased risk of side effects in the digestive tract.
- Certain medicines for high blood pressure and/or heart problems (ACE inhibitors, aldosterone antagonists): There is a risk of severe kidney problems if taken with ASA at high doses (more than 3 000 mg per day). Moreover, the blood pressure lowering effect may be reduced. If this combination is used, patients should be careful to drink sufficient amounts of fluid. Monitoring of blood pressure is recommended.
- Certain medicines against epilepsy (valproic acid): Risk of increased (side) effects of valproic acid.
- Certain medicines acting in the digestive tract (magnesium salts, aluminium salts and potassium salts, oxides and hydroxides): The effect of ASA may be diminished.
- Ibuprofen and other medicines for pain and inflammation (e.g. steroids or anti-inflammatory medicines) may decrease the cardio-protective effect of CARDASA 100 mg tablets (see also section 2 Warnings and precautions).

Please also consider

ASA used at higher doses can influence the results of laboratory tests. You should therefore inform your doctor that you are taking CARDASA 100 mg tablets.

CARDASA 100 mg tablets with alcohol

The concomitant use of CARDASA 100 mg tablets and alcohol may increase gastrointestinal side effects (increased risk of bleeding in the stomach or intestines) or side effects on the central nervous system

as well as coagulation disorders (prolonged bleeding time). You should therefore avoid drinking alcohol during treatment with CARDASA 100 mg tablets.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

First and second trimesters of pregnancy

During the first 6 months of pregnancy and if you are trying for a baby, acetylsalicylic acid may be used only if advised by your doctor. The doses used should be as low and the duration of treatment as short as possible.

Third trimester of pregnancy

During the last 3 months of pregnancy, CARDASA 100 mg tablets should not be used as there is an increased risk of complications for both mother and baby.

There is a risk of developmental disorders in the foetus (circulatory malformations and/or kidney function disorder or even kidney failure).

During labour bleeding may be increased in both mother and baby, and the duration of labour may be delayed or prolonged.

Breastfeeding

Small amounts of the active substance acetylsalicylic acid and its metabolites pass into breast milk. Short-term use of CARDASA 100 mg tablets at low doses is usually not a reason for stopping breastfeeding. However, if you have to take it for longer or at higher doses, you should discontinue breast-feeding your baby.

Fertility

CARDASA 100 mg tablets may impair the fertility of women. This effect usually reverses after stopping the treatment.

Driving and using machines

CARDASA 100 mg tablets in recommended doses may cause dizziness, which may affect the ability to drive a vehicle or operate machinery.

CARDASA 100 mg tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CARDASA 100 mg tablets

Do not share medicines prescribed for you with any other person.

Always take CARDASA 100 mg tablets exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults: 100 mg to 300 mg (1 to 3 tablets) taken every day, preferably at the same time each day.

Note: For the use of acetylsalicylic acid for pain and/or fever, medicines with higher doses are available.

Use in children and adolescents

There is no relevant use of CARDASA in children and adolescents.

In general, medicines containing acetylsalicylic acid should be used in children below 12 years only if prescribed by a doctor (see section 2 Children and adolescents).

Method of administration

The gastro-resistant tablets should be swallowed whole with some liquid with or without meals, always at the same time of the day.

Do not chew or divide CARDASA 100 mg tablets gastro-resistant tablets, since this will damage the gastro-protective coating of the medicine.

The only exception to this rule is early treatment after heart attack: in this case the tablets should be chewed for rapid onset of effect.

Duration of treatment

Your doctor will tell you for how long you should continue taking CARDASA 100 mg tablets.

If you take more CARDASA 100 mg tablets than you should

Symptoms and signs of moderate overdose may be tinnitus (ringing in the ears), hearing problems, headache, dizziness, confusion.

Severe overdose may present with fever, hyperventilation (unusually fast or deep breathing), metabolic disturbances (e.g. hyperacidity, lowering of blood sugar levels), unconsciousness, cardiovascular shock, problems with lung function.

Intoxication may be dangerous for elderly patients and particularly for young children.

Excessive therapeutic doses and accidental overdoses may be fatal.

If you took too many tablets, or if a child has accidentally ingested several tablets, contact a doctor or emergency department of the nearest hospital immediately. Take the remaining tablets or tablet pack with you so that the doctor can identify the substance taken.

If you forget to take CARDASA 100 mg tablets

Do not take a double dose to make up for a forgotten tablet, but continue with the next CARDASA 100 mg tablets dose as usual.

If you stop taking CARDASA 100 mg tablets

Talk to your doctor before you stop taking CARDASA 100 mg tablets.

If you notice side effects, your doctor will discuss these with you and will advise you on a potential change of treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Not all side effects reported for CARDASA 100 mg tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARDASA 100 mg tablets, please consult your health care provider for advice.

If any of the following happens, stop taking CARDASA 100 mg tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Skin rash, hives or itching, shortness of breath, breathing problems swelling of the face, eyelids, or lips.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CARDASA 100 mg tablets. You may need urgent medical attention or hospitalisation.

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

- Stomach pain (mild), heartburn, indigestion, nausea and vomiting, stomach ulcers, unusual bleeding, heart condition, meningitis, difficulty in breathing, swelling and hypertension.

These are all serious side effects. You may need urgent medical attention.

If any of the following side effects occur, speak to your doctor or pharmacist:

- Dizziness (with high doses), stomach pain, or bruising, vomiting blood, black stools, problems with passing urine, diarrhoea, constipation.
- Tightness of chest, and stuffy and runny nose.
- DRESS reaction (rash, facial swelling accompanied by abnormal heart rates).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CARDASA 100 mg tablets.

5. How to store CARDASA 100 mg tablets

Keep this medicine out of the sight and reach of children.

- Store at or below 30 °C.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 CARDASA 100 mg tablets contains

- The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 100 mg acetylsalicylic acid.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, potato starch, talc, triacetin, methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30%.

What CARDASA 100 mg tablets looks like and contents of the pack

CARDASA 100 mg tablets are enteric-coated tablets are white film-coated tablets, round and biconvex,

without break-score.

CARDASA 100 mg tablets comes in PVC / aluminium blisters with 30, 50 or 100 tablets per package.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Viatriis Healthcare (Pty) Ltd

4 Brewery Street

Isando

Kempton Park

Gauteng, 1601

Tel. no.: +27 11 451 1300

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