PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed without a doctor's prescription

CARTIA™

Enteric-coated tablets 100 mg

Each tablet contains:
Acetylsalicylic acid 100 mg.
Inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".
Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Take the preparation according to the dosage instructions in section 3. Consult the pharmacist if you need additional information.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for primary prevention of coronary heart disease in patients at increased risk and secondary prevention of heart and brain diseases caused by arterial thrombosis.
Therapeutic group: anticoagulant, platelet aggregation inhibitor.
Cartia inhibits the aggregation of blood platelets and in this way prevents blood clots from developing.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
• You are sensitive (allergic) to acetylsalicylic acid (the active ingredient), salicylates or to any of the additional ingredients contained in the medicine (see section 6 "Further information") • You have had a reaction in the past to certain medicines for pain, fever or inflammation (salicylates or other non-steroidal anti-inflammatory drugs), which manifested by asthma attacks or other allergic reactions • You suffer from acute gastric or intestinal ulcers • You have a tendency to disorders leading to bleeding • You suffer from kidney or liver failure • You suffer from severe heart failure which is not being adequately treated • You are concurrently taking methotrexate at a dosage of 15 mg or more per week • You are in your last trimester of pregnancy and are taking a daily dosage above 150 mg (see section "Pregnancy and breastfeeding").

Special warnings regarding use of the medicine
Before treatment with Cartia, tell the doctor if:
• You are sensitive to other pain relief, anti-inflammatory, antirheumatic medicines or other allergenic substances • You are also taking non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or naproxen (medicines to treat pain, fever or inflammation). See section 2 "Preparations that weaken the effect of the medicine" • You suffer from other allergies (with effects such as skin effects, itching or urticaria) • You suffer from bronchial asthma, hay fever (allergic rhinitis), swelling of the nasal mucosa (nasal polyps) or chronic respiratory tract disease • You are already being treated with anticoagulants (such as coumarin or heparin derivatives, with the exception of low-dosage heparin) • You have a history of gastric or intestinal ulcers or a history of gastric or intestinal bleeding • You suffer from impaired liver function • You suffer from impaired renal function or from reduced blood flow in the heart or blood vessels (such as renal vascular disease, heart failure, blood volume depletion, major surgery, sepsis or major hemorrhagic events), since acetylsalicylic acid may further increase the risk of impaired renal function and acute renal failure • You are about to undergo surgery, including minor surgery (e.g., dental extraction surgery); there may be an increased tendency to bleed. Inform the doctor or dentist that you are taking Cartia • You know that you have severe glucose-6-phosphate-dehydrogenase (G6PD) enzyme deficiency. Acetylsalicylic acid may cause breakdown or accelerated disintegration of the red blood cells or a certain type of anemia. Factors that may increase the risk of this are, for example: high dosage, fever or acute infections.
Additional warnings
• At low dosages, acetylsalicylic acid reduces the excretion of uric acid. This condition may cause a gout attack under certain circumstances in predisposed patients • If you get cut or are injured, the bleeding may continue for longer than usual. This is related to the activity of the medicine. Minor cuts or injuries (e.g., when shaving) are generally not problematic. In case of unusual bleeding (in an unusual place or for an unusual length of time), consult the doctor • Do not take medicines containing acetylsalicylic acid for prolonged periods or at high dosages without consulting a doctor.
Children and adolescents
The medicine is intended for adults over the age of 18. Under this age, consult a doctor. Do not use Cartia in children or adolescents with febrile illnesses unless instructed to do so by a doctor and other therapeutic measures have failed. Prolonged vomiting in conjunction with such an illness may be a sign of Reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.
Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
Preparations that increase the effect of the medicine to the extent that there is an increased risk of side effects:
• Anticoagulants (such as coumarin, heparin) and thrombolytic medicines: acetylsalicylic acid may increase the risk of bleeding if taken before treatment with thrombolytic agents. Pay attention to external and internal signs of bleeding (such as bruising) if you are undergoing such treatment • Other platelet aggregation inhibitors (medicines that inhibit platelet coagulation), such as ticlopidine, clopidogrel: increased risk of bleeding • Medicines containing cortisone or cortisone-like substances (with the exception of those that are used for topical treatment or cortisone replacement therapy for Addison's disease) there is an increase risk of bleeding and ulcers in the stomach and intestines • Alcohol: increased risk of ulcers and bleeding in the stomach and intestines • Other pain relief and anti-inflammatory medicines (non-steroidal anti-inflammatory drugs) and antirheumatic medicines with salicylic acid: increased risk of gastrointestinal ulcers and bleeding • Medicines for diabetes, such as insulin, tolbutamide, glibenclamide (so called sulfonylurea) in combination with acetylsalicylic acid at high dosages: blood glucose level may be reduced • Digoxin (a medicine to strengthen the heart muscle contraction) • Methotrexate (to treat cancer and certain rheumatic disorders) • Valproic acid (to treat epilepsy) • Antidepressants from the SSRI group: increased risk of gastrointestinal bleeding.
Preparations that weaken the effect of the medicine:
• Certain medicines that increase the excretion of urine (diuretics: aldosterone antagonists, such as spironolactone, canrenoate, loop diuretics such as furosemide) • Certain medicines to treat hypertension (especially ACE inhibitors) • Medicines to treat gout that increase the excretion of uric acid (such as probenecid, benzbromarone) • Some non-steroidal anti-inflammatory drugs (NSAIDs) (except acetylsalicylic acid) such as ibuprofen and naproxen: reduced effect of Cartia on inhibition of platelet agglutination and clotting; may reduce the protective effect of the medicine against heart attacks and stroke • Metamizole (a preparation intended to reduce pain and fever): when both medicines are taken together, the effect of acetylsalicylic acid on platelet aggregation may be reduced. Therefore, this combination should be used with caution in patients taking a low dosage of Cartia to protect the heart.
Before using acetylsalicylic acid, inform the doctor about other medicines you are taking. If you are using acetylsalicylic acid regularly, consult the doctor before taking any other medicine, including non-prescription medicines.
Do not take Cartia with any of the medicines listed above unless explicitly instructed to do so by a doctor.
Use of the medicine and alcohol consumption
Do not consume alcohol during the course of treatment with acetylsalicylic acid.
Pregnancy and breastfeeding
If you are pregnant or breastfeeding, if you suspect that you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before using this medicine.
Pregnancy
First and second trimester
Do not take Cartia during the first and second trimesters of pregnancy unless necessary and only when instructed by a doctor. If you need to be treated during this period or when you are trying to become pregnant, use the lowest possible dosage for the shortest possible amount of time. Starting from week 20 of pregnancy, if you take Cartia for more than a few days, the preparation may cause kidney problems in the unborn baby, which may lead to low amniotic fluid that surrounds the baby (oligohydramnios), or to narrowing of one of the blood vessels (ductus arteriosus) in the heart of the unborn baby. This effect may occur close to the time treatment with Cartia is started and is usually reversible upon discontinuation of treatment with the preparation. If low amniotic fluid or narrowing of the blood vessel in the heart of the unborn baby is diagnosed, stop treatment with Cartia immediately. If you need treatment for more than a few days, the doctor may recommend closer monitoring (with emphasis on the amount of amniotic fluid and on the blood vessels in the heart of the unborn baby).
Last trimester
During the last trimester of pregnancy, acetylsalicylic acid, the active ingredient in Cartia, must not be taken at a dosage of exceeding 150 mg per day, due to an increased risk of complications for the mother and child before and during the birth (including an increased risk of miscarriage and certain birth defects; see also section "Do not use the medicine if:"). During the last trimester of pregnancy, dosages of up to 150 mg of Cartia per day may only be taken on instruction by the doctor.
Breastfeeding
Small amounts of acetylsalicylic acid and its metabolites pass into breast milk. No negative effects on the baby have been reported to date, so you do not have to stop breastfeeding as long as the daily dosage does not exceed 150 mg. However, stop breastfeeding when using higher dosages (more than 150 mg daily).
Driving and operating machinery
No special precautionary measures are necessary.
Important information about some of the ingredients of the medicine
The medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e., it is essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The recommended dosage is generally: one tablet per day.
Take the first tablet in accordance with the day indicated on the blister (tray).
Do not exceed the recommended dose.
Duration of treatment
Cartia in intended for long-term use. The attending doctor should determine the length of treatment.
Mode of administration
Swallow the tablet whole with plenty of water, at least half an hour before a meal.
Do not crush, chew or halve the tablet, because the medicine has an enteric (protective) coating.
Do not hold the medicine in your mouth for longer than it takes to swallow it.
If you accidentally take a higher dosage
Dizziness and ringing in the ears can be signs of serious poisoning, particularly in children and elderly patients. Inform the doctor immediately if you suspect you took an overdose. The doctor will decide which measures should be taken depending on the severity of the overdose taken.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of medicine with you.
If you forgot to take the medicine
If you forgot to take this medicine at the scheduled time, continue to take a dose as described above in section 3 "How should you use the medicine", or as determined by the doctor, but never take two doses together to make up for a forgotten dose!
If you stop taking the medicine
Even if there is an improvement in your health, do not stop taking Cartia without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cartia may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
If you experience any of the side effects listed below, stop taking Cartia and inform the doctor so that he will be able to evaluate the severity of the side effect and decide what to do.
Stop using Cartia immediately at the first signs of hypersensitivity (see below under rare side effects).
Common side effects (effects that occur in up to one user in 10):
• Gastric and intestinal problems, such as heartburn, nausea and vomiting, abdominal pain and diarrhea • Minor blood loss from the stomach and intestine.
Uncommon side effects (effects that occur in up to one user in 100):
• Skin reactions [in very rare cases, there may be severe eruptions of skin rash involving the mucous membranes and fever (erythema exsudativum multiforme)] • Gastric and intestinal bleeding. Prolonged use of Cartia may cause anemia (due to iron deficiency) as a result of occult blood loss from the stomach and intestine • Gastric and intestinal ulcers, which, in very rare cases, may lead to perforation • Gastric and intestinal inflammation.
Refer to the doctor immediately if you notice black stools or vomiting of blood (signs of serious bleeding in the stomach, please see section "Countermeasures", below).
Rare side effects (effects that occur in up to one user in 1,000):
• Hypersensitivity reactions of the skin, the respiratory system, the stomach and intestine and cardiovascular system, particularly in asthmatic patients. The symptoms can be: a drop in blood pressure, attacks of breathing difficulty, inflammation of nasal mucosa, stuffy nose, anaphylactic shock (severe and acute allergic reaction), swelling of the face, tongue and throat (angioedema).
Very rare side effects (effects that occur in up to one user in 10,000):
• Elevated liver enzyme values • Renal impairment and acute renal failure • Reduced blood sugar levels (hypoglycemia) • At low dosages, acetylsalicylic acid reduces the excretion of uric acid. This condition may cause a gout attack in predisposed patients under certain circumstances.
Side effects whose exact frequency is unknown:
• Headache, dizziness, confusion, impaired hearing or tinnitus (ringing in the ears) can be signs of an overdosage, especially in children and elderly patients (see "If you accidentally take a higher dosage") • There have been reports of severe bleeding events, such as bleeding in the brain (particularly in patients with uncontrolled hypertension and/or combined treatment with anticoagulants). These are rare to very rare reports, with some of the cases being life-threatening • Accelerated breakdown or disintegration of red blood cells and a certain type of anemia in patients with severe glucose-6-phosphate-dehydrogenase (G6PD) deficiency • Bleeding: nosebleed, bleeding gums, skin bleeding or bleeding from the urinary tract and genitals, possibly with prolongation of the bleeding time. This effect can persist for 4 to 8 days after use • If there is pre-existing damage to the intestinal mucosa, membranes may form in the intestinal cavity which may cause blockage.
Countermeasures:
Stop taking Cartia if you experience any of the effects listed above, and inform the doctor, who will decide what should be done, depending on the severity of the side effect.
Stop taking Cartia permanently at the first sign of a hypersensitivity reaction.
If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
Additionally, you can report to the company via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor • Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month • Do not use if the package is ripped or damaged • **Storage conditions:** store below 25°C • Do not discard medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following inactive ingredients:
Guar gum, Talc, Methylacrylic acid copolymer, Hypromellose 6cp, Titanium dioxide, Polyvinyl alcohol, PEG 3350, Triethyl citrate, FD&C Yellow #6, Triacetin, Colloidal anhydrous silica, Sodium bicarbonate, Sodium lauryl sulfate.
• What the medicine looks like and the contents of the package: Cartia is an orange-colored tablet with an enteric (protective) coating. The tablets come in a blister package (tray) containing 28 tablets • Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham • Manufacturer and address: Aspen Pharma Pty Ltd., Dandenong, Victoria, Australia • Revised in August 2024 • Registration number of the medicine in the National Drug Registry of the Ministry of Health: 5089.26384