

PATIENT PACKAGE INSERT ACCORDING TO 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 ingredients and allergens in the medicine: See section 6 in the leaflet **"Additional information"**.

Read this entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

You should take the medicine according to the dosage instructions in section 3. Consult the pharmacist if you need further information.

1. What is the medicine intended for?

The medicine is intended for the primary prevention of coronary heart disease in high-risk patients and the secondary prevention of heart and brain diseases caused by arterial thrombosis.

Therapeutic group: Anticoagulants, blood 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 hypersensitive (allergic) to acetylsalicylic acid (the active ingredient), salicylates or to any of the other ingredients this medicine contains (see section 6 **"Additional information"**).
- you have had a reaction in the past to certain medicines for pain, fever, or inflammation (salicylates or other non-steroidal anti-inflammatory medicines), that was manifested by asthma attacks or other allergic reactions.
- you suffer from acute gastric or intestinal ulcers.
- you have a pathological tendency to bleed.
- you suffer from kidney or liver failure.
- you suffer from severe heart failure that is not being treated adequately.
- you are concurrently taking **methotrexate** at a dosage of 15 mg or more per week.
- you are in the last trimester of pregnancy, and are taking a daily dosage over 150 mg (see section **"Pregnancy and breastfeeding"**).

Special warnings regarding the use of this medicine

Before treatment with Cartia, tell the doctor if:

- you are sensitive (allergic) to other analgesics, anti-inflammatory, antirheumatic (for rheumatism) medicines, or other allergenic substances.
- you are also taking non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or naproxen (medicines for treatment of pain, fever, or inflammation). See section 2 "Medicines that weaken the effect of this medicine".
- you suffer from other allergies (with effects such as skin reactions, itching, or urticaria).
- you suffer from bronchial asthma, hay fever (allergic rhinitis), swelling of the nasal mucosa (nasal polyps), or a chronic respiratory disease.
- you are already being treated with anticoagulant medicines (such as coumarin or heparin derivatives, with the exception of low-dose heparin).
- you have gastric or duodenal ulcers, or a history of gastrointestinal bleeding.
- you suffer from impaired liver function.
- you suffer from impaired renal function or impaired function of the cardiovascular system (such as a renal vascular disease, congestive heart failure, decreased blood volume, major surgery, sepsis, or major hemorrhagic events), since acetylsalicylic acid may further increase the risk of renal function impairment and acute renal failure.
- you are about to undergo surgery, including minor surgery (such as dental extraction surgery); there may be an increase in the tendency to bleed. Tell the doctor or dentist that you are taking Cartia.
- you know you have a severe Glucose-6-phosphate-dehydrogenase (G6PD) enzyme deficiency. Acetylsalicylic acid may cause accelerated hemolysis or breakdown 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 trigger a gout attack in predisposed patients.
- if you get cut or injured, the bleeding may last longer than usual. This has to do with the action of the medicine. Cuts or minor injuries (e.g. when shaving) are generally insignificant. If you experience unusual bleeding (at a non-typical 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 above the age of 18 years. Below this age, refer to the doctor. Do not use Cartia in children or adolescents with febrile illnesses unless instructed to do so by a doctor and when other therapeutic measures have failed. Prolonged vomiting in conjunction with such an illness could be a sign of Reye 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 medicines without a doctor's prescription and nutritional supplements, tell the doctor or pharmacist. Particularly if you are taking:

Medicines that increase the effect of this medicine to the extent that there is an increased risk of side effects:

- Anticoagulants (such as coumarin, heparin) and thrombolytic medicines: acetylsalicylic acid can increase the risk of bleeding if taken before treatment with thrombolytic medicines. Pay attention to signs of external and internal bleeding (such as bruising), if you are being treated with such therapy.
- Other platelet aggregation inhibitors (medicines that inhibit platelet coagulation) such as ticlopidine, clopidogrel: increased risk for bleeding.

- Medicines containing cortisone or cortisone-like substances (with the exception of those used for topical treatment or cortisone replacement therapy for Addison's disease); the risk for gastrointestinal bleeding and ulcers is increased.
- Alcohol: increased risk for gastrointestinal ulcers and bleeding.
- Other analgesics and anti-inflammatory medicines (non-steroidal anti-inflammatory drugs) and antirheumatic medicines with salicylic acid: increased risk for gastrointestinal ulcers and bleeding.
- Antidiabetics such as insulin, tolbutamide, glibenclamide (also known as sulfonylurea) combined with high dosages of acetylsalicylic acid: the blood glucose level may drop.
- Digoxin (a medicine that causes increased intensity of heart muscle contraction).
- Methotrexate (to treat cancer and certain rheumatoid disorders).
- Valproic acid (to treat epilepsy).
- Antidepressants from the SSRIs group: increased risk for gastrointestinal bleeding.

Medications that weaken the effect of this medicine:

- Certain medicines that increase urine output (diuretics): aldosterone antagonists such as spironolactone, carenonate, loop diuretics such as furosemide).
- Certain medicines to treat hypertension (in particular 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: decrease of the anti-platelet aggregation and clotting effect: may reduce the protection of the medicine against heart attack and stroke.
- Metamizole (a medicine intended to reduce pain and fever): may reduce the effect of acetylsalicylic acid on platelet aggregation when both medicines are taken together. Therefore, this combination should be used with caution in patients taking low-dose Cartia to protect the heart.

Before using acetylsalicylic acid, inform the doctor about other medicines that you are taking. If you use acetylsalicylic acid regularly, consult the doctor before taking other medicines, including non-prescription medicines.

Do not take Cartia together with any of the aforementioned medicines unless explicitly instructed to do so by a doctor.

Use of this medicine and alcohol consumption
Do not consume alcohol during treatment with the medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, if you suspect that you are pregnant or are planning to conceive, consult a doctor or pharmacist before using this medicine.

Pregnancy

During the first and second trimester of pregnancy, Cartia should only be taken if instructed by a doctor. During the last trimester of pregnancy, acetylsalicylic acid, the active ingredient in Cartia, should not be taken at a dosage that exceeds 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 a day of Cartia may only be taken if instructed so by a doctor.

Breastfeeding

Small quantities of acetylsalicylic acid and its metabolites pass into breast milk. No negative effects on the baby have been reported to date and therefore it is unnecessary to stop breastfeeding if the **daily dosage does not exceed 150 mg**. However, if higher dosages are taken (more than 150 mg daily) breastfeeding should be stopped.

Driving and operating machinery

No special precautions are necessary.

Important information about some of the ingredients of this medicine

Each tablet of Cartia contains 0.05 mg sodium, that is to say essentially "sodium-free".

3. How should you use this medicine?

You should check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The recommended dosage is usually: one tablet a day.

Take the first tablet according to the day written on the blister (tray).

Do not exceed the recommended dose.

Treatment duration:

Cartia is intended for long-term use. The attending doctor should decide the treatment duration.

Manner of treatment

Swallow the tablet whole with plenty of water at least half an hour before a meal.

Do not crush, chew, or halve the tablet since the medicine has an enteric (protective) coating.

Do not hold the tablet in your mouth beyond the time necessary to swallow it.

If you have accidentally taken a higher dosage
Dizziness and ringing in the ears may be signs of serious poisoning, particularly in children and elderly patients. Inform the doctor immediately if you suspect that you took an overdose. The doctor will decide which measures should be taken according to the degree of overdose taken.

If you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

If you forgot to take the medicine at the scheduled time, continue taking a dose as described above in section **"How should you use this medicine?"** or as recommended by the doctor, but do not under any circumstances take two doses together to compensate for the forgotten dose!

If you stop taking this 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 a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, the 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 mentioned below, stop taking Cartia and inform the doctor, so that he/she can determine the severity of the side effect and decide on further action.

With the onset of first signs of hypersensitivity, immediately stop using Cartia (see as follow in rare side effects).

Common side effects (effects that appear in up to one out of 10 users):

- Heartburn
- Nausea and vomiting, abdominal pain
- Diarrhea
- Minor blood loss from the digestive system

Uncommon side effects (effects appear in up to one out of 100 users):

- Skin reactions [in very rare cases, possibly a severe skin rash eruption with mucosal involvement and fever (Erythema exudativum multiforme)].
- Gastrointestinal bleeding. Prolonged use of Cartia may cause anemia (due to iron deficiency) as a result of occult blood loss from the digestive system. Severe gastrointestinal bleeding may manifest as black stools or vomiting of blood.
- Gastrointestinal ulcers, which in very rare cases may lead to perforation.
- Gastrointestinal inflammation.

Refer immediately to the doctor if you observe black stools or vomiting of blood (signs of severe bleeding in the stomach, please see below section "Countermeasures").

Rare side effects (effects that appear in up to one out of 1,000 users):

- Hypersensitivity reactions of the skin, the respiratory system, the digestive system, and the cardiovascular system, particularly in asthmatic patients. The signs can be: a drop in blood pressure, attacks of breathing difficulties, inflammation of nasal mucosa, stuffy nose, allergic reactions, swelling of the face, tongue, and throat (angioedema).

Very rare side effects (effects that appear in up to one out of 10,000 users):

- Elevated liver values.
- Impaired kidney function and acute renal failure.
- Drop in blood sugar levels (hypoglycemia).
- At low dosages, acetylsalicylic acid reduces the excretion of uric acid. This condition may trigger a gout attack in predisposed patients.

Side effects whose exact frequency is unknown:

- Headache, dizziness, confusion, impaired hearing or tinnitus (ringing in the ears) can be signs of an overdose, particularly in children and elderly patients (see **"If you accidentally took a higher dosage"**).
- Cases of serious bleeding such as cerebral bleeding have been reported (particularly in patients with uncontrolled hypertension and/or in concomitant treatment with anticoagulants). These reports are rare to very rare, and which in isolated cases were life-threatening.
- Accelerated hemolysis or breakdown of the red blood cells and a specific form of anemia in patients suffering from severe Glucose-6-phosphate-dehydrogenase (G6PD) deficiency.
- Bleeding: nosebleed, bleeding gums, skin bleeding, or bleeding in the urinary tract and genitals, and bleeding time may be prolonged. This phenomenon 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 later be accompanied by intestinal stenosis.

Countermeasures:

Stop taking Cartia if you experience the side effects listed above and inform your doctor who will decide which measures to take depending on the severity of the side effect.

Stop taking Cartia permanently with the first sign indicative of a hypersensitivity reaction.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) which directs 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: www.perrigo-pharma.co.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants, 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 torn or damaged.

Storage conditions: Store at below 25°C.

Do not discard medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional 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 contents of the package:

Cartia is an orange-colored tablet with an enteric (protective) coating. The tablets are packaged in a blister pack (tray) containing 28 tablets.

Registration Holder and address: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.

Manufacturer and address: Aspen Pharma Pty Ltd., Dandenong, Victoria, Australia.

Revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 5089.26384

11.10.21

Cartia PIL PB1021-07