

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Aspirin C

Effervescent tablets

Active ingredients

Each effervescent tablet contains:

Acetylsalicylic acid 400 mg

Ascorbic acid (Vitamin C) 240 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve after 4 days.

1) What is this medicine intended for?

Aspirin C is intended for pain relief, fever reduction, anti-rheumatic treatment.

Therapeutic group: nonsteroidal anti-inflammatory drugs (NSAIDs).

2) Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to acetylsalicylic acid, other salicylates, ascorbic acid or any of the other ingredients that this medicine contains (see section 6 'Additional information' for a list of inactive ingredients).
- you have previously had a hypersensitivity reaction to certain medications for pain, fever or inflammation (salicylates or other nonsteroidal anti-inflammatory drugs) in the form of asthma attacks or in another form.
- you have acute ulcers in your stomach or bowel.
- you have an abnormally increased tendency to bleed.
- you have liver or kidney failure.
- you have severe heart failure that is not controlled despite medication therapy.
- you are concurrently taking 15 mg or more methotrexate a week.
- you are in the last three months of pregnancy.
- you have or ever had kidney stones
- you have high levels of oxalic acid in your urine.
- you have an iron storage disease (haemochromatosis).

Special warnings about using this medicine

Before you start taking Aspirin® C, tell your doctor if:

- you are sensitive to other pain-relief, anti-inflammatory or antirheumatic medicines or other allergy-triggering substances.
- you have allergies (such as skin reactions, itching, hives [urticaria]), asthma, hay fever, swelling of the nasal mucosa (polyps in the nose), or chronic respiratory diseases.

- you are concurrently taking anticoagulant medicines (see below in the 'Medicines that reinforce the effect of this medicine to the extent that the risk of side effects is higher' section).
- you have a history of stomach or intestinal ulcers or bleeding.
- you have impaired liver function.
- you have impaired kidney function or reduced blood flow to the heart and/or blood vessels (for example kidney vascular disease, heart failure, reduced blood volume, major surgical procedure, blood poisoning, or severe bleeding): acetylsalicylic acid may further increase the risk of damage to your kidney function and acute kidney failure.
- before surgical procedures (including minor procedures such as tooth extraction): there may be an increased tendency to bleed. Tell your doctor or dentist that you have taken Aspirin C.
- you have severe glucose-6-phosphate dehydrogenase (G6PD) deficiency. Acetylsalicylic acid may induce accelerated breakdown or disintegration of red blood cells or a certain type of anemia. Factors that increase the risk of this are for example: high dosage, fever or acute infections.

Additional warnings:

Prolonged use of pain relievers may cause headaches, potentially causing you to take more pain relievers which in turn may cause persistent headaches.

Habitual use of pain relievers may cause permanent kidney damage with a risk of kidney failure. This risk is particularly high when taking several different types of pain relievers at the same time.

At low doses acetylsalicylic acid reduces the excretion of uric acid. This may trigger a gout attack under certain circumstances in predisposed patients.

Children and adolescents

This medicine is intended for adults. Do not use this medicine in children or in adolescents without first consulting a doctor. Do not use Aspirin C in children or adolescents with feverish illnesses unless instructed to do so by a doctor and when other treatment measures have failed. Prolonged vomiting in this condition could 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, or if you are about to take other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. The effect of the medicines or groups of medicines listed below may be affected if you take Aspirin C at the same time.

Medicines that reinforce the effect of this medicine to the extent that the risk of side effects is higher:

- **Medicines that prevent blood clotting** (such as coumarin, heparin) **and medicines that break down blood clots:** acetylsalicylic acid can increase the risk of bleeding if taken before such treatment. Pay attention to signs of external or internal bleeding (such as bruising) if you are to have such treatment.
- **Medicines that prevent blood platelets from clumping** (such as ticlopidine, clopidogrel): increased risk of bleeding.
- **Other medicines that relieve pain and reduce inflammation** (pain relievers/nonsteroidal anti-inflammatory drugs) taken together with a dosage of 7 or more Aspirin C tablets a day: increased risk of ulcers or bleeding in the digestive system.
- **Medicines containing cortisone or cortisone-like substances** (with the exception of products applied to the skin or cortisone replacement therapy for Addison's disease): increased risk of side effects in the digestive system.
- **Digoxin** (a medicine to strengthen the heart muscle contraction).
- **Medicines that reduce blood sugar levels** (for diabetes): blood sugar level may drop significantly.

- **Methotrexate** (a medicine used to treat cancer and certain rheumatic disorders). See above in the 'Do not use this medicine if' section.
- **Valproic acid** (a medicine used to treat brain seizures [epilepsy]).
- **Selective serotonin re-uptake inhibitors (SSRIs)** (certain medicines used to treat depression): increased risk of bleeding in the digestive system.

Medicines that weaken the effect:

- **Diuretics** (medicines that increase the excretion of urine) taken together with a dosage of 7 or more Aspirin C tablets a day.
- Medicines for lowering blood pressure that belong to a group called **ACE inhibitors**, taken together with a dosage of 7 or more Aspirin C tablets a day.
- **Medicines for gout that increase the excretion of uric acid** (such as probenecid, benzbromarone).
- **Deferoxamine** (antidote in cases of iron poisoning): potential deterioration of heart function if taken together with ascorbic acid (vitamin C).

Effects of the medicine on laboratory tests

The determination of the levels of sugar, uric acid, creatinine, carbamazepine and uric acid in urine may be affected. Testing for blood in the stool may also produce false-negative results.

Using this medicine and food

Do not take this medicine on an empty stomach.

Using this medicine and alcohol consumption

Alcohol increases the risk of gastrointestinal ulcers and bleeding.

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

In the last trimester:

Do not take Aspirin C in the last trimester of pregnancy because this could harm your unborn child or cause problems during childbirth. The medicine can cause kidney and heart problems in your unborn baby. It can affect the mother and child's tendency to bleed and lead to the birth process being delayed or taking longer than expected.

In the first and second trimester:

In the first and second trimesters of pregnancy, do not take acetylsalicylic acid unless it is absolutely necessary and only by doctor's orders. If you have to be treated during this time or while you are trying to conceive, use the lowest dosage possible and given for the shortest possible time. If you take acetylsalicylic acid for more than two days from the 20th week of pregnancy, the medicine may cause kidney problems in your unborn child, which can lead to a reduction in the amount of amniotic fluid surrounding your baby (oligohydramnios), or to narrowing of one of the blood vessels (ductus arteriosus) in your unborn baby's heart. This may happen shortly after starting treatment with Aspirin C and is generally reversible when treatment with the medicine is stopped. If a reduction in the amount of amniotic fluid or narrowing of your unborn baby's blood vessels is diagnosed, stop treatment with Aspirin C immediately. If you have to be treated for more than a few days, your doctor may recommend closer monitoring (focusing on the amount of amniotic fluid and the blood vessels in the unborn baby's heart).

Breastfeeding

Small amounts of acetylsalicylic acid and its metabolites pass into breast milk. As there are no reports of side effects in breastfed babies, it is not necessary to stop breastfeeding if this medicine is used occasionally at the recommended dose. However, if you will be using this medicine for a prolonged period or at a high dosage, you must stop breastfeeding your baby.

Fertility

This medicine belongs to a group of medicines called nonsteroidal anti-inflammatory drugs which may affect a woman's fertility. This effect is reversible once the medicine is discontinued.

Driving and using machines

No special precautions are necessary.

Important information about some of this medicine's ingredients

Each effervescent tablet of Aspirin C contains 466.4 mg sodium. This amount is equivalent to about 23% of the maximum recommended daily intake of sodium for adults. If you are keeping to a low-sodium diet, take this into account. Talk to your doctor or pharmacist if you need one or more tablets a day for an extended period, especially if you have been told to follow a low-sodium diet.

3) How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Adults:

1-2 tablets every 4-6 hours, but no more than 8 tablets in 24 hours.

Children and adolescents:

Only use in children after consulting a doctor.

Only a doctor will determine the dose and how this medicine should be taken. The recommended dose in children of 9-12 years old is one effervescent tablet, up to 3 times a day.

Please read the instructions for use in children and adolescents in section 2 under 'Children and adolescents'.

Patients with liver or kidney impairment

Acetylsalicylic acid should be used with caution in patients with liver impairment or kidney impairment. See above in section 2 'Special warnings about using this medicine').

Do not exceed the recommended dose.

Treatment duration

You may take a single dose at intervals of 4-6 hours, as needed, but do not take more than 8 tablets in 24 hours.

Do not take Aspirin C for longer than 4 days without consulting your doctor/dentist.

Method of administration

Dissolve the effervescent tablets completely in a glass of water and drink it all immediately. Do not take this medicine on an empty stomach.

There is no information about crushing/splitting/chewing the tablets.

If you have accidentally taken a higher dose, immediately tell your doctor who will decide which measures are necessary depending on the severity of the overdose/poisoning. You may experience ringing in your ears (tinnitus), hearing problems, sweating, nausea, vomiting, headaches, and dizziness. These signs may indicate severe poisoning, particularly in children and elderly patients.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) Side effects

Like all medicines, using Aspirin C may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following list of side effects includes all the side effects reported following use of acetylsalicylic acid, even those reported after long-term use at high doses in gout patients. Except for isolated cases, the frequency information is based on short-term use at maximum daily doses of 3 grams of acetylsalicylic acid.

Stop taking this medicine and consult your doctor immediately if you experience:

- hypersensitivity reactions in the respiratory system, digestive system, and heart and circulatory system, particularly in asthma patients. The following symptoms or signs may occur: drop in blood pressure, difficulty breathing, inflammation of the mucous membranes of the nose, stuffy nose, anaphylactic shock, swelling of the face, tongue and throat (angioedema).
- hypersensitivity reactions such as serious skin reactions (including severe skin rashes with fever and involving the mucous membranes [exudative erythema multiforme]).

These reactions are rare (affect 1-10 in 10,000 users).

Consult your doctor immediately if you experience:

- black stools or vomiting blood (signs of severe bleeding in the stomach): occur rarely (affect 1-10 in 10,000 users).

Common side effects (affect 1-10 in 100 users):

- stomach and intestinal disorders such as heartburn, diarrhoea, nausea, vomiting, stomach ache.

Uncommon side effects (affect 1-10 in 1,000 users):

- hypersensitivity reactions such as skin reactions.

Rare side effects (affect 1-10 in 10,000 users):

- serious bleeding, such as brain haemorrhage (especially in patients with uncontrolled high blood pressure and/or patients treated at the same time with medications that prevent blood clotting). This may be life-threatening in some cases.
- bleeding in the stomach and intestine that may in very rare cases result in iron deficiency (anemia). Consult your doctor immediately if you have black stools or bloody vomit (may be signs of serious bleeding in the stomach).
- ulcers in the stomach and intestine which may, in very rare cases, cause perforation.
- inflammation in the stomach and intestine.

Very rare side effects (affect less than one in 10,000 users):

- increase in liver enzyme values.

Side effects whose frequency is unknown (cannot be estimated from the currently available data):

- accelerated breakdown or disintegration of red blood cells and a certain type of anaemia in patients who have severe glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- impaired kidney function and acute kidney failure.
- bleeding, for example nosebleeds, bleeding gums, appearance of bruises or bleeding in the urinary tract and genitals, with the possibility of prolonged bleeding time. This effect can persist for 4 to 8 days after use.
- headaches, dizziness, hearing problems, ringing in your ears and confusion - may be signs of an overdose.
- When there is prior damage to the intestinal mucosa, membranes can form in the intestine, possibly resulting in a blockage (particularly with long-term use).

The following list of side effects includes all the side effects reported following use of ascorbic acid (vitamin C).

Side effects whose frequency is unknown (cannot be estimated from the currently available data):

- diarrhoea, nausea, vomiting, pain in the stomach and intestine, stomach ache.
- hypersensitivity reactions, allergic shock.

Stop taking Aspirin C if you experience any of the side effects described above, and contact your doctor. This is so that your doctor can determine their severity and decide how to continue your treatment. **If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5) How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C.

6) Additional information

- In addition to the active ingredients, this medicine also contains:
Sodium hydrogen citrate, sodium hydrogen carbonate, citric acid, sodium carbonate
- **What the medicine looks like and contents of the pack**
Aspirin C is a white effervescent tablet embossed on one side with 'Bayer'.
Tablets are packaged in blister trays of 10 or 20 tablets. Not all pack sizes may be marketed.
- **Registration holder/importer's name and address:** Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

- Registration number of the medicine in the Ministry of Health's National Drug Registry: 057 86 24955 00.

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