



Instructions for use: information for users

Aspirin®-C

Effervescent tablet with 400 mg acetylsalicylic acid and 240 mg ascorbic acid

Please read the entire patient information leaflet carefully as it contains important information on using the medicine.

This medicine is available on a non-prescription basis. To achieve the best possible therapeutic results, you must nonetheless use Aspirin-C as directed.

- Keep the patient information leaflet – you may wish to read it again later.
- If you have any further questions or need advice, please consult your pharmacist.
- If your condition worsens or has not improved within 4 days, you must consult a doctor.
- If any of the mentioned side effects affects you seriously or if you notice any side effects that are not listed in this patient information leaflet, inform your doctor or pharmacist.

This leaflet contains:

1. What is Aspirin-C and what is it used for?
2. What should you be aware of before taking Aspirin-C?
3. How should Aspirin-C be taken?
4. What side effects may occur?
5. How should Aspirin-C be stored?
6. Further information

1. WHAT IS ASPIRIN-C AND WHAT IS IT USED FOR?

Aspirin-C has analgesic, antipyretic and anti-inflammatory properties (nonsteroidal anti-inflammatory / analgesic).

Aspirin-C is indicated for:

- Mild to moderate pain such as headache, dental pain, period pain, painful symptoms associated with colds (e.g. headache, sore throat, aching limbs)
- Fever

Please note the instructions for adolescent (see section 2 “adolescent”).

2. WHAT SHOULD YOU BE AWARE OF BEFORE TAKING ASPIRIN-C?

Aspirin-C must not be used:

- if you are hypersensitive (allergic) to acetylsalicylic acid, other salicylates, ascorbic acid or any of the other ingredients of Aspirin-C;
- if you have a history of reacting hypersensitively to special drugs against pain, fever or inflammation (salicylates or other nonsteroidal anti-inflammatory drugs) with asthma attacks or the like;
- if you have acute gastric or duodenal ulcers;
- if you have a pathologically increased tendency to bleed;
- if you have liver or kidney failure;
- if you have severe, non-stabilized heart failure (cardiac insufficiency);
- if you are concurrently taking 15 mg or more methotrexate per week;
- during the last trimester of pregnancy.

Particular caution is required when using Aspirin-C:

- if you are hypersensitive to other analgesics, special drugs against inflammation or rheumatism (anti-inflammatory/antirheumatic drugs) or other allergenic substances;
- if you have allergies (e.g. skin reactions, itching, nettle rash), asthma, hay fever, nasal polyps or chronic respiratory tract infections;
- if you are undergoing concomitant treatment with anticoagulant drugs;
- if you have a history of gastric or duodenal ulcers or gastrointestinal bleeding;

- if you have impaired liver function;
- in patients with impaired renal function or patients with impaired cardiovascular circulation (e.g. renal vascular disease, congestive heart failure, volume depletion, major surgery, sepsis or major hemorrhagic events), since acetylsalicylic acid may further increase the risk of renal impairment and acute renal failure;
- before surgery (including minor surgery such as dental extractions); increase in bleeding tendency can occur. Please inform your doctor or dentist if you have taken Aspirin-C;
- in patients suffering from severe glucose-6-phosphate dehydrogenase deficiency; acetylsalicylic acid may induce hemolysis or hemolytic anemia. Factors that may increase the risk of hemolysis are e.g. high dosage, fever or acute infections;
- if you have renal calculi (calcium oxalate urolithiasis);
- if you suffer from an iron storage disease (thalassaemia, haemochromatosis).

What other precautions must be taken?

Long-term consumption of analgesics can cause headaches which, if treated with more analgesics, can in turn lead to perpetuation of the headache.

Habitual use of analgesics can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy). The risk is particularly great when several different analgesics are taken concomitantly.

At low doses acetylsalicylic acid reduces the excretion of uric acid. This may cause a gout attack in predisposed patients.

Adolescent

Aspirin-C should not be taken by adolescents with feverish illnesses unless they have been instructed to do so by a doctor and other therapeutic measures have failed. Prolonged vomiting in conjunction with such illnesses could be a sign of Reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.

Interactions with other drugs

Please inform your doctor or pharmacist if you are taking/using other medicines or have taken/used other medicines recently, even if they are non-prescription medicines.

The effects of the medicines or groups of substances below may be affected by concomitant treatment with Aspirin-C.

Enhanced effects ranging up to an increased risk of side effects:

- **Anticoagulants** (e.g. coumarin, heparin) and **thrombolytic medicines**: acetylsalicylic acid can increase the risk of bleeding if taken before thrombolytic treatment. You must therefore pay attention to signs of external or internal bleeding (e.g. bruising) if you are undergoing such treatment;
- Drugs that inhibit the clotting of blood platelets (**platelet aggregation inhibitors**), e.g. Ticlopidine, Clopidogrel: increased risk for bleedings;
- Other drugs **against pain or inflammation** (nonsteroidal analgesics / anti-inflammatory drugs) at doses of 7 effervescent tablets Aspirin-C per day and more: increased risk of gastrointestinal ulcers and bleedings;
- Drug products containing **cortisone** or **cortisone-like substances** (with the exception of products that are applied topically or cortisone replacement therapy for Addison's disease): increased risk of gastrointestinal side effects;
- **Alcohol**: elevated risk of gastrointestinal ulcers and -bleeding;
- **Digoxin** (a drug to strengthen the heart muscle);
- **Drugs to reduce blood glucose** (antidiabetics): the blood glucose level can be reduced;
- **Methotrexate** (a drug for treatment of cancer diseases and certain rheumatic disorders);
- **Valproic acid** (a drug for treatment of convulsions of the brain [epilepsy]);
- **Selective serotonin re-uptake inhibitors** (SSRIs): increased risk of gastrointestinal bleedings.

Weakening of effects:

- **Diuretics** (drugs to increase urine excretion) at doses of 7 effervescent tablets Aspirin-C per day and more;
- **ACE inhibitors** (a class of drugs reducing blood pressure) at doses of 7 effervescent tablets Aspirin-C per day and more;

- **Gout remedies** that promote the excretion of uric acid (e.g. probenecid, benzbromarone);
- **Deferoxamine:** Concurrent use with ascorbic acid may enhance tissue iron toxicity, especially in the heart, causing cardiac decompensation.

Pregnancy and lactation

Before taking any medicines consult your doctor or pharmacist.

Aspirin-C should not be taken during the first and second trimester of pregnancy. Consult your doctor before taking Aspirin-C.

Acetylsalicylic acid, the drug substance of Aspirin-C must not be taken during the last trimester of pregnancy due to an increased risk of complications for mother and baby before and during the birth. This medicine belongs to a group of drugs (non-steroidal antiphlogistics) which could impair woman's fertility. This effect is reversible following discontinuation of the medication.

The drug substance acetylsalicylic acid and its derivatives will pass in little amounts into the milk. It is not necessary to interrupt breast-feeding for short-term use at the recommended dosage because there are no known effects on the baby.

However, in case of long-term or high-dose usage, the infant should be weaned.

Driving and operating machinery

No special precautions are necessary.

Important warning about certain ingredients of Aspirin-C

One effervescent tablet contains 20.3 mmol (466.4 mg) sodium. If you have to follow a low-salt diet, you should take this into account.

3. HOW SHOULD ASPIRIN-C BE TAKEN?

Always take Aspirin-C exactly as directed in the patient information leaflet. Please ask your doctor or pharmacist if you are unsure how to take this medicine.

Dosage

Unless otherwise prescribed by your doctor, the usual dose is:

Age	Single dose	Total daily dose
Adolescents* and adults	1-2 effervescent tablets	3-6 effervescent tablets

* Please note the instructions for adolescent (see section 2 "adolescent").

Mode of administration

Dissolve the effervescent tablets completely in a glass of water and drink the entire content of the glass immediately.

You should **not take Aspirin-C on an empty stomach.**

Duration of administration

The single dose can be taken at intervals of 4 to 8 hours if necessary, up to a maximum of 3 doses a day. The maximum daily dose must not be exceeded.

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

What should you do if you take too much Aspirin-C?

Tinnitus, feeling of impaired hearing, sweating, nausea, vomiting, headache and vertigo, particularly in elderly patients, may indicate serious poisoning.

Please notify your doctor if you suspect an overdose of Aspirin-C. He will decide on the necessary measures to be taken depending on the severity.

4. WHAT SIDE EFFECTS MAY OCCUR?

Like all medicines, Aspirin-C can have side effects, which must not occur in all patients.

The following adverse effects comprise all reported side effect following treatment with acetylsalicylic acid, including those following long-term high-dose therapy in rheumatism patients. The incidence figures for events that go beyond isolated cases are based on short-term use of daily doses of not more than 3 g acetylsalicylic acid.

The following incidence rating is used to evaluate the frequency of side effect:

Very Common: more than 1 treated patient of 10
Common: 1 to 10 treated patients of 100

Uncommon:	1 to 10 treated patients of 1,000
Rare:	1 to 10 treated patients of 10,000
Very rare:	less than 1 treated patient of 10,000
Not known:	frequencies can not estimated from available data

Common:

Gastrointestinal disorders such as heartburn, nausea, vomiting, abdominal pain.

Uncommon:

Hypersensitivity reactions such as skin reactions.

Rare:

- Severe bleedings such as cerebral bleeding, particularly in patients with non-stabilised hypertension and/or concomitant treatment with anticoagulants, which in isolated cases could be life-threatening.
- Gastrointestinal bleeding which in very rare cases can lead to iron deficiency anaemia. If you pass black stools or vomit blood (signs of serious bleeding in the stomach), you must inform your doctor immediately.
- Gastrointestinal ulcers which in very rare cases can lead to perforation.
- Hypersensitivity reactions of the respiratory system, gastrointestinal tract and of the cardiovascular system, particular in asthmatics.
The following symptoms may occur: a drop in blood pressure, attacks of difficult breathing, rhinitis, nasal congestion, allergic shock, swelling of the face, tongue and larynx (angioedema).
- Hypersensitivity reactions such severe skin reactions (up to severe feverish skin rash with mucosa involvement [erythema exsudativum multiforme]).
- Gastrointestinal inflammation.

Very rare:

Increased liver values.

Frequency not known:

- Hemolysis and hemolytic anemia in patients with severe forms of glucose-6-phosphate dehydrogenase (G6PD) deficiency have been reported.
- Renal impairment and acute renal failure.
- Bleeding, e.g. nosebleeds, bleeding gums, skin bleeding or urogenital bleedings, possibly with prolongation of the bleeding time. This effect can persist for 4 to 8 days after use.
- Headache, dizziness, impaired hearing ability; tinnitus and mental confusion can be signs of an overdose.

If you experience any of the above-mentioned side effects, **do not take any more Aspirin-C.**

Notify your doctor so that he can determine the severity of the side effect(s) and decide on any necessary further action.

Inform your doctor or pharmacist if any of the mentioned side effects affects you seriously or if you notice any side effects that are not listed in this patient information leaflet.

5. HOW SHOULD ASPIRIN-C BE STORED?

Keep medicines out of the reach of children.

The expiry date of this product is printed on the effervescent tablet strip and the cardboard box. Do not use the product after this date.

Storage condition: Do not store above 25°C!

6. FURTHER INFORMATION

What contains Aspirin-C?

The active ingredients are: acetylsalicylic acid and ascorbic acid.

1 Effervescent tablet contains: 400 mg acetylsalicylic acid (Ph-Eur.) and 240 mg ascorbic acid (Ph-Eur).

The excipients are: sodium dihydrogen citrate, sodium hydrogen carbonate, citric acid, sodium carbonate (anhydrous).

Dosage form and content:

Aspirin-C is a white effervescent tablets with one-side Bayer-cross-embossing.

Package with 10 effervescent tablets is available.

Manufacturer:

Bayer Bitterfeld GmbH, Germany

for Bayer Consumer Care AG, Basel, Switzerland

Date of information: September 2011

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists