

Package leaflet: Information for the user

Acetylsalicylzuur ratiopharm 500 mg, tabletten

acetylsalicylic acid

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days (for fever) or 3 - 4 days (for pain).

What is in this leaflet

1. What <product name> is and what it is used for
2. What you need to know before you use <product name>
3. How to use <product name>
4. Possible side effects
5. How to store <product name>
6. Contents of the pack and other information

1. What <product name> is and what it is used for

<product name> contains acetylsalicylic acid. Acetylsalicylic acid is an analgesic (pain-relief) and an antipyretic (fever-reducer).

<product name> is used for the symptomatic treatment of fever and/or mild to moderate pain such as headaches, flu symptoms, dental pain and muscular pain.

<Product name> is indicated for adults and adolescents 12 years of age and older.

Ask your doctor or pharmacist about other forms of acetylsalicylic acid for patients weighing less than 40 kg. You must talk to a doctor if you do not feel better or if you feel worse after 3 days (for fever) or 3 - 4 days (for pain).

2. What you need to know before you use <product name>

Do not use <product name> if you:

- are allergic to acetylsalicylic acid or other salicylates, or any of the other ingredients of this medicine (listed in section 6).
- have a history of asthma or allergic reactions caused by acetylsalicylic acid or to a related medicine (notably non-steroidal anti-inflammatory drugs).
- have a stomach or intestinal (including duodenal) ulcer.
- have a risk of bleeding (haemorrhagic condition).
- have severe kidney, liver or heart failure.
- are being treated with methotrexate in doses of more than 15 mg/week.
- are being treated with oral anticoagulants (medicines to thin the blood and to prevent it from clotting) and have a history of gastroduodenal ulcer.
- are in the last three months of pregnancy (see “Pregnancy, breast-feeding and fertility”)

If you are in any doubt if this medicine should be used, ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using <product name> if you:

- are being treated with other products containing acetylsalicylic acid, to avoid the risk of overdose.
- use pain killers regularly. This may lead to reduced kidney function. Several pain killers used in combination make this more likely.
- have a hereditary disease affecting red blood cells (Glucose-6-phosphate dehydrogenase deficiency). Elevated doses of acetylsalicylic acid could lead to a destruction of red blood cells (haemolysis).
- have a history of stomach or intestinal ulcers, stomach or intestinal bleeding or gastritis.
- have impaired kidney or liver function.
- have asthma: Asthma attacks, in some patients, may be related to allergic reactions to non-steroidal anti-inflammatory drugs or to acetylsalicylic acid (see “Do not use <product name>”).
- suffer from heavy menstrual bleeding.
- take medicines used against gout. Acetylsalicylic acid reduces the elimination of uric acid in the blood (see section 2. Other medicines and <product name>).
- are breast-feeding. It is not recommended to use this medicine while breast-feeding (see section “Pregnancy, breast-feeding and fertility”).

Other warnings:

- if gastrointestinal bleeding (bleeding from mouth, blood in feces, black colour of feces) occurs during the treatment, you must stop the treatment immediately and call your doctor or an emergency medical service.
- tell your doctor, surgeon, anesthetist or dentist in case a surgery, even if minor, is envisaged. Acetylsalicylic acid increases bleeding (hemorrhagic risks) even in low doses and even if it is taken several days before.
- if headaches occur while taking acetylsalicylic acid or other pain killers over a prolonged period, do not increase your dosage, rather seek the advice of your doctor or pharmacist.

Children

Reye's syndrome (a rare yet very serious disease primarily associated with neurological and liver damage) has been observed in children suffering from viral illnesses and being administered acetylsalicylic acid. As a result:

- in the case of a viral sickness such as the flu or chicken pox, administration of acetylsalicylic acid to a child should not be done without the prior consultation of a doctor;
- if signs of dizziness or fainting, altered behaviour, or vomiting occur in a child taking acetylsalicylic acid, notify your doctor immediately.

Other medicines and <product name>

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

Do not take <product name>:

- if you are being treated with methotrexate in doses of more than 15 mg per week.
- if you are being treated with blood thinners (oral anticoagulants) and have a history of gastroduodenal ulcer (see section 2. Do not use <product name>).

Talk to your doctor or pharmacist before taking acetylsalicylic acid with any of the following:

- non-steroidal anti-inflammatory drugs
- blood thinners (oral anticoagulants)
- heparins
- medicines that dissolve blood clots (thrombolytics)
- platelet aggregation inhibitors, e.g. clopidogrel, ticlopidine
- uricosuric medications used in the treatment of gout (e.g. benzbromarone, probenecid).
- glucocorticoids (excluding hydrocortisone replacement therapy)
- pemetrexed

- anagrelide
- medicines that treat water retention (diuretics)
- angiotensin converting enzyme inhibitors, angiotensin II receptor antagonists
- methotrexate used at doses of 15 mg or less per week
- gastrointestinal topicals, antacids and charcoal
- deferasirox
- selective serotonin re-uptake inhibitors (example: citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline)

To avoid any interaction effects between medications, you should alert your doctor or pharmacist to any other medications that you take.

<Product name> with alcohol

Do not take <product name> with alcohol.

Pregnancy, breast-feeding and fertility

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

Pregnancy

Do not take acetylsalicylic acid during the last 3 months of pregnancy as this may cause serious harm to you or your child.

In the first six months of pregnancy you should consult your doctor before taking this medicine or other products containing acetylsalicylic acid.

If you have taken this medicine during pregnancy, you should immediately contact your doctor.

Breast-feeding

This medicine can pass into the mother's breast milk. It is not recommended to use this medicine if you are breast-feeding.

Fertility

The product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

Acetylsalicylic acid has no influence on the ability to drive and use machines.

3. How to use <product name>

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For oral use only. Take tablet(s) with plenty of liquid.

Dosage

Adults and adolescents (aged 16 and older)

- The recommended single dose is 1 tablet, and can be taken again if needed after a minimum of 4 hours. For more intense fever or pain, the recommended single dose is 2 tablets, and can be taken again if needed after a minimum of 4 hours.
- **The total daily dose should not exceed 6 tablets.**

Elderly patients (aged 65 years and older)

- The recommended single dose is 1 tablet, and can be taken again if needed after a minimum of 4 hours.
- **The total daily dose should not exceed 4 tablets.**

Adolescents aged 12 - 15 years (weighing 40 – 50 kg):

- The recommended single dose is 1 tablet, and can be taken again if needed after a minimum of 4 hours.
- **The total daily dose should not exceed 4 tablets.**

Children under 12 years of age (weighing less than 40 kg)

Ask your doctor or pharmacist about other available formulations of acetylsalicylic acid for patients weighing less than 40 kg.

Patients with impaired liver function, impaired kidney function or cardiovascular problems (e.g. with heart failure or major bleeding events)

Acetylsalicylic acid should be used with caution. Seek the advice of your doctor or pharmacist (see section 2. Do not use <product name>).

Do not take this medicine for more than 3 days (for fever) or 3 - 4 days (for pain) unless directed by a physician.

If you use more <product name> than you should

If you take too much acetylsalicylic acid, it is possible that you experience ringing of the ears, a sensation of hearing loss, headaches or dizziness. These are signs typical of an overdose. Stop treatment and contact a doctor immediately.

If you forget to use <product name>

Do not take a double dose to make up for a forgotten dose.

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.

Frequencies: not known: frequency cannot be estimated from the available data.

Possible side-effects due to acetylsalicylic acid are:

Side effects can get serious and you may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the nearest hospital if you notice any of the following:

- bleeding (nose bleed, bleeding gums, red spots under the skin, etc.)
- allergic reactions such as a rash, asthma attack or facial swelling accompanied with difficulty breathing
- headache, dizziness, sensation of hearing loss, tinnitus (ringing in the ears), which are usually indicative of an overdose
- bleeding in the brain
- rhinitis (inflammation of the nose), dyspnoe (shortness of breath), bronchospasm (narrowing of the airways)
- stomach ache, dyspepsia, nausea (feeling sick), vomiting
- gastrointestinal bleeding (bleeding from mouth, blood in feces or black colour of feces). These occur more frequently in elderly patients and when taking high doses (see section 2. “Warnings and precautions”)
- gastric ulcers and perforations
- increase of liver enzymes mainly reversible when the treatment is stopped, liver impairment (mainly liver cells)
- urticaria, severe skin reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme
- impaired kidney function

- Reye's syndrome (disturbance of consciousness or abnormal behaviour, or vomiting) in a child presenting a viral disease and taking acetylsalicylic acid (see section 2. What you need to know before you use <product name>)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <product name>

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

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Store in the original package, in order to protect from moisture.

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 <product name> contains

- The active substance is acetylsalicylic acid (Ph.Eur.).
Each tablet contains 500 mg acetylsalicylic acid (Ph.Eur.).
- The other ingredients are maize starch, powdered cellulose.

What <product name> looks like and contents of the pack

White, round, biconvex tablet with cross break score on one side, diameter approx. 12 mm and height approx. 5.5 mm.

The tablet can be divided into equal halves.

The cross break score is only to facilitate breaking for ease of swallowing and not to divide into equal quarters.

<product name> is available in blister packs (white opaque PVC foil/Aluminum foil) containing 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ratiopharm GmbH
Graf-Arco-Strasse 3
87079 Ulm
Duitsland

Manufacturer

Merckle GmbH
Graf-Arco-Str.3

89079 Ulm
Duitsland

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren
Duitsland

In het register ingeschreven onder:
RVG 126642

This medicinal product is authorised in the Member States of the EEA under the following names:

DE: ASS-ratiopharm 500 mg Tabletten

NL: Acetylsalicylzuur ratiopharm 500 mg, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in februari 2022.