

Package leaflet: Information for the user

Aspirin Rowex 75 mg Gastro-resistant tablets

Acetylsalicylic acid

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Aspirin Rowex is and what it is used for
2. What you need to know before you take Aspirin Rowex
3. How to take Aspirin Rowex
4. Possible side effects
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1. What Aspirin Rowex is and what it is used for

Aspirin Rowex contains acetylsalicylic acid, which in low doses belong to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina; in the brain it can cause a stroke.

Aspirin Rowex can only be used as a preventive treatment. It is taken to reduce the risk of blood clots forming and thereby prevent further:

- heart attacks
- strokes
- cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).

Aspirin Rowex is also used to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

This medicinal product is not recommended for emergencies.

2. What you need to know before you take Aspirin Rowex

Do not take Aspirin Rowex if you

- are allergic to acetylsalicylic acid or any of the other ingredients of this medicine (listed in section 6)
- are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used for arthritis or rheumatism and pain
- have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs
- currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke
- have ever had the problem of your blood not clotting properly
- have severe liver or kidney problems
- have severe heart problems which can cause shortness of breath or ankle swelling
- are in your last 3 months of pregnancy; you must not use higher doses than 100 mg per day (see section "Pregnancy and breast-feeding")

- are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.

Warnings and precautions

Talk to your doctor before taking Aspirin Rowex if you:

- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have high blood pressure
- are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack
- have ever had gout
- have heavy menstrual periods
- suffer from a deficiency of the enzyme glucose- 6-phosphate dehydrogenase (G6PD).

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section “Possible side effects”).

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction). Acetylsalicylic acid is blood-thinning and there may be an increased risk of bleeding which may persist for a period of 4–8 days after you stop taking acetylsalicylic acid.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of acetylsalicylic acid at the same time may result in deterioration of kidney function.

This medicinal product is not suitable as a pain killer or fever reducer.

Do not take Aspirin Rowex with other medicines that contain acetylsalicylic acid (such as e.g. aspirin) or with other pain relievers and anti-inflammatory drugs (NSAIDs, such as ibuprofen).

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist.

Children and adolescents

Acetylsalicylic acid may cause Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease which affects the brain and liver and can be life-threatening. For this reason, Aspirin Rowex should not be given to children and adolescents younger than 16 years, unless on the advice of a doctor.

Other medicines and Aspirin Rowex

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

The effect of treatment may be influenced if acetylsalicylic acid is taken at the same time as some other medicines for:

- thinning of the blood/prevention of blood clots (e.g. warfarin, heparin, clopidogrel, ticlopidine, dipyridamole, cilostazol, alteplase)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics, ACE-inhibitors, angiotensin II receptor antagonists, calcium-channel blockers)
- regulation of the heartbeat (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen, other products containing acetylsalicylic acid or steroids)
- gout (e.g. probenecid, sulfinpyrazone)
- epilepsy (valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses below 15 mg per week; for doses higher than 15 mg per week see section “Do not take Aspirin Rowex” above)
- diabetes (e.g. glibenclamide, insulin)

- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine).
- use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids).

Aspirin Rowex with alcohol

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time. Therefore, the use of alcohol is not recommended.

Pregnancy and breast-feeding

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.

Pregnant women should not take acetylsalicylic acid during pregnancy unless advised by their doctor. You should not take Aspirin Rowex if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100 mg (see section “Do not take Aspirin Rowex”). Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

Breast-feeding women should not take acetylsalicylic acid unless advised by their doctor.

Driving and using machines

Aspirin Rowex has no or negligible influence on the ability to drive and use machines.

Aspirin Rowex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Aspirin Rowex

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Prevention of heart attacks:

- The recommended dose is 75-150 mg once daily.

Prevention of strokes:

- The recommended dose is 75-300 mg once daily.

Prevention of cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain):

- The recommended dose is 75-150 mg once daily.

Prevention formation of blood clots after certain types of heart surgery:

- The recommended dose is 75-150 mg once daily.

Elderly

Recommended dose as for adults. In general, acetylsalicylic acid should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Use in children and adolescents

Acetylsalicylic acid should not be given to children and adolescents younger than 16 years, unless on the advice of a doctor (see section 2 “Children and adolescents”).

Method of administration

For oral use.

The tablets should be swallowed whole with sufficient water (1/2 glass of water), preferably after a meal. The tablets have a gastro-resistant coating which prevents irritant effects on the gut, and should therefore not be crushed, broken or chewed.

If you take more Aspirin Rowex than you should

If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact immediately the nearest casualty department. Show any left over medicines or the empty packet to the doctor.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

If you forget to take Aspirin Rowex

If you miss a dose, wait until it is time for your next dose, then go on as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Aspirin Rowex

Do not interrupt or stop your treatment with Aspirin Rowex, without having previously agreed this with your doctor.

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.

The most common side effects are disorders in the stomach or gut, including nausea and vomiting.

If you notice any of the following rare but serious side effects, stop taking Aspirin Rowex and contact a doctor immediately:

Rare side effects (may affect up to 1 in 1,000 people):

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction)
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome.
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools
- Changes in behavior with nausea and vomiting could be an early sign of Reye's syndrome, a possibly fatal disease which requires immediate medical treatment (see also section 2 "Children and adolescents").

Common side effects (may affect up to 1 in 10 people):

- Nausea, vomiting, diarrhoea
- Indigestion
- Minor bleeding in the stomach.

Uncommon side effects (may affect up to 1 in 100 people):

- Hives
- Ulcers in stomach or small intestine and perforation
- Stomach inflammation.

Rare side effects (may affect up to 1 in 1,000 people):

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells
- Inflammation in the blood vessels
- Bruising with purple spots (cutaneous bleeding)

- Severe skin reactions such as rash known as erythema multiforme and its life threatening forms Stevens-Johnson syndrome and Lyell's syndrome
- Hypersensitivity reactions in the skin, respiratory tract, gastrointestinal tract and cardiovascular system, especially in those with asthma. Symptoms may be fall in blood pressure, difficulty breathing, swelling of e.g. lips, face or body, or shock.
- Reye's syndrome (a very rare disease in children which affects the brain and liver (see section 2 "Children and adolescents")
- Prolonged bleeding time.

Very rare side effects (may affect up to 1 in 10,000 people):

- Increased uric acid in the body
- Low blood sugar
- Anaemia due to breakdown of red blood cells
- Impaired kidney function, acute renal failure
- Increased liver enzymes.

Side effects with frequency not known (frequency cannot be estimated from the available data):

- Ringing in your ears (tinnitus) or reduced hearing ability
- Headache
- Dizziness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aspirin Rowex

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

Store below 25°C.

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

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

Do not throw away any medicines via wastewater. 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 Aspirin Rowex contains

- The active substance is acetylsalicylic acid.
Each gastro-resistant tablet contains 75 mg of acetylsalicylic acid.
- The other ingredients are:
tablet core: microcrystalline cellulose, maize starch, colloidal anhydrous silica, stearic acid;
film-coating: methacrylic acid – ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate, talc.

What Aspirin Rowex looks like and contents of the pack

Aspirin Rowex gastro-resistant tablets 75 mg are oval, white, biconvex film-coated tablet, 9.2 x 5.2 mm.

Pack sizes blisters:

10, 20, 28, 30, 50, 56, 60, 90, 100 gastro-resistant tablets.

Pack sizes unit dose blisters:

10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 90 x 1, 100 x 1 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun ZTN 3000, Malta.

Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Str., 2600 Dupnitsa, Bulgaria.

Actavis hf., Reykjavikurvegur 76-78, IS-220 Hafnarfjordur, Iceland.

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

SE	Acetylsalicylsyra Hexal 75 mg enterotabletter
BE	ASA Sandoz 75 mg maagsapresistente tabletten
IE	Aspirin Rowex 75 mg Gastro-resistant tablets
LU	ASA Sandoz 75 mg comprimés gastro-résistants
PL	Acetylsalicylic Acid Sandoz 75 mg, tabletki dojelitowe
RO	ACID ACETILSALICILIC SANDOZ 75 mg COMPRIMATE GASTROREZISTENTE
SI	Acetilsalicilna kislina Lek 75 mg gastrotezistentne tablete

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