

This product has different legal status in different countries.
For current legal status in Sweden, please refer to the approved Swedish package leaflet published on MPAs Webb site.

Package leaflet: information for the patient

Esteprin 75 mg gastro-resistant tablets Esteprin 100 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 Esteprin is and what it is used for
2. What you need to know before you take Esteprin
3. How to take Esteprin
4. Possible side effects
5. How to store Esteprin
6. Contents of the pack and other information

1. What Esteprin is and what it is used for

Esteprin 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.

Esteprin 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).

Esteprin 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. It can only be used as a preventive treatment.

2. What you need to know before you take Esteprin

Do not take Esteprin:

- if you are allergic to acetylsalicylic acid or any of the ingredients of this medicine (listed in section 6),
- if you have experienced allergic reactions like asthma in association with salicylates or substances with a similar mechanism of action, especially non-steroidal anti-inflammatory drugs (NSAIDs),
- if you currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like bleeding in the brain,
- if you have ever had the problem of your blood not clotting properly,
- if you have severe liver or kidney problems,
- if you are in the last three months of your pregnancy; you must not use higher doses than 100 mg per day (see section “Pregnancy, breast-feeding and fertility”),
- if you 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 or pharmacist before taking Esteprin if you:

- are taking other salicylates or other nonsteroidal anti-inflammatory drugs (medicines for pain, fever, inflammation or rheumatism),
- if you have severe heart muscle weakness that is not sufficiently controlled by medication (heart failure),
- have trouble with your kidneys, liver or heart,
- have or have ever had problems with your stomach or small intestine, or inflammation of the stomach lining (gastritis)
- have high blood pressure,
- are asthmatic, are allergic to other drugs, especially other salicylates or non-steroidal anti-inflammatory drugs (NSAID), 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.

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) or if you take medicines that may increase the risk of bleeding (e.g. anticoagulants, thrombolytics) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding or prolonged bleeding time.

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, Esteprin should not be given to children aged under 16 years, unless on the advice of a doctor.

Medicines containing acetylsalicylic acid should not be taken for extended periods of time or in high doses without consulting a doctor.

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.

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

Other medicines and Esteprin

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 clots (e.g. warfarin, heparin, clopidogrel),
 - rejection of organ after transplantation (cyclosporine, tacrolimus),
 - high blood pressure (e.g. diuretics and ACE-inhibitors),
 - regulation of the heart beat (digoxin),
 - manic-depressive illness (lithium),
 - pain and inflammation (e.g. NSAIDs such as ibuprofen, or steroids, or metamizole)
- Metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose acetylsalicylic acid for cardioprotection,
- gout (e.g. probenecid, sulfinpyrazone),
 - epilepsy (valproate, phenytoin),
 - glaucoma (acetazolamide),
 - cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week),
 - diabetes (e.g. glibenclamide),
 - 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).

Estepirin with food, drink and alcohol

The gastro-resistant tablets can be taken with or without food.

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

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.

If you continue or start treatment with Estepirin during pregnancy per instruction of the physician, then use Estepirin as advised by your doctor and do not use a higher dose than is recommended.

Pregnancy - last trimester

Do not take Estepirin higher than 100 mg per day if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

If you take Estepirin at low doses (up to and including 100 mg per day), you need strict obstetric monitoring as advised by your doctor.

Pregnancy – first and second trimester

You should not take Estepirin during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Estepirin can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

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

Driving and using machines

Estepirin should not affect your ability to drive and use machines.

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

3. How to take Esteprin

Always take this medicine exactly as your doctor or pharmacist 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

As for adults. In general, acetylsalicylic acids 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 administered to children and adolescents younger than 16 years, unless prescribed by a doctor (see section "Warnings and precautions").

Method of administration

For oral use.

The tablets should be swallowed whole with sufficient fluid (1/2 glass of water). 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 Esteprin 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, decreased potassium in your blood (resulting with weakness, feeling tired with muscle cramps and/or abnormal heart rhythm), bleeding in your stomach or intestine (resulting with vomiting blood and/or black, tarry stool), dizziness, somnolence with difficulty in concentrating, mental confusion with agitation, reduced alertness and motivation, shallow breathing, problems with your kidneys, shortness of breath and difficulty of breathing with coughing up frothy sputum, seizures, hallucinations, low blood sugar, coma and shock.

If you forget to take Esteprin

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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Esteprin and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction) (rare).
- 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 (rare).
- Distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching; (frequency not known)
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools (frequency not known).
- Ulcers in the mouth, fever and infection(s) (agranulocytosis - a severely lowered count of white blood cells) (rare).

Possible side effects listed below are grouped by frequency of occurrence.

Common side effects (affects 1 to 10 users in 100):

- indigestion,
- increased tendency for bleeding,

Uncommon side effects (affects 1 to 10 users in 1,000):

- hives,
- runny noses,
- breathing difficulty.

Rare side effects (affects 1 to 10 users in 10,000):

- severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells,
- nausea and vomiting,
- cramps in the lower respiratory tract, asthma attack,
- 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, such as swelling of e.g. lips, face or body, or shock,
- abnormal heavy or prolonged menstrual periods.

Not known side effects (frequency cannot be estimated from the available data):

- ringing in your ears (tinnitus)
- headache,
- vertigo,
- ulcers in stomach or small intestine and perforation,
- prolonged bleeding time,
- impaired kidney function,
- impaired liver function,
- high level of uric acid in the blood.
- pruritus, rash,
- increased liver enzymes

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 Esteprin

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 /blister after EXP. The expiry date refers to the last day of that month.

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 Esteprin contains

The active substance is acetylsalicylic acid.

Each gastro-resistant tablet contains 75 mg acetylsalicylic acid.

Each gastro-resistant tablet contains 100 mg 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) dispersion 30%, polysorbate 80, sodium laurilsulfate, triethyl citrate, talc.

What Estepirin looks like and contents of the pack

Estepirin gastro-resistant tablets 75 mg are white, oval, biconvex gastro-resistant tablets, 9.2 x 5.2 mm.
Estepirin gastro-resistant tablets 100 mg are white, round, biconvex gastro-resistant tablets with a diameter of 7.2 mm.

Pack sizes:

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

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

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in August 2025