

PACKAGE LEAFLET

Package leaflet: Information for the user

Acetylsalicylsyra Evolan 75 mg film-coated 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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] 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.

[Invented name] 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).

[Invented name] is also used in the treatment of acute heart attack and to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

2. What you need to know before you take [Invented name]

Do not take [Invented name] if you

- are allergic to acetylsalicylic acid or any of the 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
- suffer from gout
- 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”)
- 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 [Invented name] 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

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”).

When taking acetylsalicylic acid, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately when you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

Tell your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

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 medicine 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.

Acetylsalicylsyra Evolan contains sodium

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

Children and adolescents

This medicine must not be given to children and adolescents younger than 16 years, unless prescribed by a doctor.

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

Other medicines and [Invented name]

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 (such as. warfarin, heparin, clopidogrel)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (such as. diuretics and ACE-inhibitors)
- regulation of the heart beat (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (such as. NSAIDs such as ibuprofen, or steroids)
- 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 (such as. probenecid)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- diabetes (such as. 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)
- antacids (indigestion medicine)

[Invented name] with alcohol

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

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.

If your doctor advises you to continue or start treatment with [Invented name] during pregnancy, follow their instructions carefully and do not take a higher dose than the recommended.

Pregnancy - last trimester

Do not take [Invented name] 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 [Invented name] 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 [Invented name] 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, [Invented name] 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.

You should not take acetylsalicylic acid during breast-feeding unless advised by your doctor.

Driving and using machines

[Invented name] should not affect your ability to drive and use machines.

3. How to take [Invented name]

Always use 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 75-160 mg once daily.

Prevention of strokes:

The recommended dose is 75-325 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 75-160 mg once daily.

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

The recommended dose is 75-160 mg once daily.

Acute heart attack

The recommended dose is 150-450 mg, taken as soon as possible after onset of symptoms.

Use in 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.

Method of administration

For oral use.

If you take more [Invented name] 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 leftover 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 [Invented name]

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 medicine, 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 [Invented name] and contact a doctor immediately:

- 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

Other side effects:

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

- indigestion
- increased tendency for bleeding

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

- hives
- runny noses
- breathing difficulty

Rare (may affect up to 1 in 1000 people):

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

Unknown frequency (frequency cannot be estimated from the available data)

- ringing in your ears (tinnitus) or reduced hearing ability
- headache
- vertigo
- ulcers in stomach or small intestine and perforation
- prolonged bleeding time
- kidney function problems
- salt or water retention which may cause swelling of hands, feet, legs, stomach, breasts or face.
- liver function problems
- high level of uric acid in the blood
- acute myocardial ischemia (painful heart condition caused by lack of blood flow to the heart) with or without myocardial infarction (heart attack) occurring as part of an allergic reaction (Kounis syndrome).

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 **[To be completed nationally]**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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

Blister: Do not store above 30°C.

Bottle: This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton or tablet container/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 [Invented name] contains

- The active substance is acetylsalicylic acid. Each tablet contains 75 mg of acetylsalicylic acid.
- The other ingredients are:
tablet core- maize starch, sodium starch glycolate (type A)
film coating- talc, macrogols, titanium dioxide (E171), glycerol monocaprylocaprate
poly(vinyl alcohol), partially hydrolyzed

What [Invented name] looks like and contents of the pack

[Invented name] 75 mg film-coated tablets are white, round biconvex film-coated tablets

Pack sizes:

Blister of PVC / PVdC / Al foil: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 200 and 300 tablets.

HDPE jar with dryer: 100, 101, 102, 103, 104, 105, 110 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Evolan Pharma AB

Box 120

182 12 Danderyd

Sweden

Manufacturer

Balkanpharma Dupnitsa AD
3, Samokovsko Shosse Str.
2600 Dupnitsa
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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}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last approved in

2026-07-31

<[To be completed nationally]>