

Package leaflet: Information for the patient

Acetylsalicylic acid Bluefish 75 mg tablets Acetylsalicylic acid Bluefish 160 mg 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 Acetylsalicylic acid Bluefish is and what it is used for
2. What you need to know before you take Acetylsalicylic acid Bluefish
3. How to take Acetylsalicylic acid Bluefish
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1. What Acetylsalicylic acid Bluefish is and what it is used for

Acetylsalicylic acid Bluefish is a so-called blood thinner agent, which reduces the risk of blood clotting by preventing the blood platelets clumping together.

Acetylsalicylic acid Bluefish is used by patients who have severe angina in the heart (unstable angina pectoris) or who have a history of cardiac or cerebral infarction (stroke). Acetylsalicylic acid Bluefish helps reduce the risk of relapse of a new infarction, by preventing clots forming in the heart and the brain's blood vessels.

2. What you need to know before you take Acetylsalicylic acid Bluefish

Do not take Acetylsalicylic acid Bluefish 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 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 or pharmacist before taking Acetylsalicylic acid Bluefish 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”).

Inform 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.

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, Acetylsalicylic acid Bluefish should not be given to children aged under 16 years, unless on the advice of 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 Acetylsalicylic acid Bluefish

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)
- 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)
- 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)
- antacids (indigestion medicine)

Acetylsalicylic acid Bluefish with alcohol

Acetylsalicylic acid Bluefish in combination with alcohol can increase the risk of bleeding in the gastrointestinal tract.

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 Acetylsalicylic acid Bluefish during pregnancy per instruction of the physician, then use Acetylsalicylic acid Bluefish as advised by your doctor and do not use a higher dose than is recommended.

Pregnancy - last trimester

Do not take Acetylsalicylic acid Bluefish 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 Acetylsalicylic acid Bluefish 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 Acetylsalicylic acid Bluefish 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, Acetylsalicylic acid Bluefish 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

Acetylsalicylic acid is excreted in human milk but is unlikely to affect nursing infants. Nevertheless, talk to your doctor if Acetylsalicylic acid Bluefish is taken more than occasionally during lactation.

Acetylsalicylic acid Bluefish can, like many anti-inflammatory drugs (NSAIDs), make it more difficult to become pregnant and is therefore not recommended for women trying to get pregnant.

Driving and using machines

Acetylsalicylic acid Bluefish has no known effects on the ability to drive and use machines.

3. How to take Acetylsalicylic acid Bluefish

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

The dose should be determined by the doctor who adjusts it individually for you.
The usual dose is 1 tablet 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").

If you take more Acetylsalicylic acid Bluefish than you should

If you take too much medicine, or if a child has taken medicine by accident, contact your doctor or hospital for the assessment of risk and advice.

If you forget to take Acetylsalicylic acid Bluefish

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, pharmacist or nurse.

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 Acetylsalicylic acid and immediately contact a doctor.

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

- Bleeding in the gastrointestinal tract, can appear as dark stool.
- Brain hemorrhage, possible symptoms may be numbness or paralysis of the face, arms and legs, often on one side of the body, difficulties speaking, confusion, disturbed vision, dizziness, balance problems, severe headache.
- Serious skin rash such as:
 - Reddish rash that often appears first on the upper body, appearing as target-like or round spots, often with blisters in the center, peeling, sores in the mouth, throat, nose, eyes and around the genitals. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
 - Widespread skin rash, fever and enlarged lymph nodes which appear approximately 2–6 weeks (possibly up to 8 weeks) after treatment begins (drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)).

Other side effects

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

Indigestion, increased risk of bleeding.

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

Hypersensitivity reactions such as urticaria, allergic rhinitis and asthma.

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

Renal effects.

People with known allergy or asthma are at increased risk of hypersensitivity reactions. Small loss of blood may in rare cases lead to anemia.

Dizziness and tinnitus can be a symptom of overdose.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. 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 Acetylsalicylic acid Bluefish

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

Do not store above 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. 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 Acetylsalicylic acid Bluefish contains

- The active substance is acetylsalicylic acid.
- *75 mg tablets*: Each tablet contains 75 mg of acetylsalicylic acid.
- *160 mg tablets*: Each tablet contains 160 mg of acetylsalicylic acid.
- The other ingredients are magnesium oxide (E 530), microcrystalline cellulose (E 460), maize starch, gelatin, colloidal anhydrous silica (E 551), talc (E 553b) and stearic acid (E 570).

What Acetylsalicylic acid Bluefish looks like and contents of the pack

75 mg tablets: White to off-white, clear to mottled, 6.5 mm, round, biconvex, uncoated tablets plain on both sides.

160 mg tablets: White to off-white, clear to mottled, 8.5 mm, round, biconvex, uncoated tablets with break line on one side and plain on the other side.

The tablets are packed in HDPE bottles with a polypropylene (PP) screw cap and silica gel desiccant.

75 mg tablets: 100, 105 and 500 tablets

160 mg tablets: 100 and 105 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and 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
Sweden	Acetylsalicylic acid Bluefish
Iceland	Acetylsalicylic acid Bluefish 75 mg/ 160 mg töflur

This leaflet was last revised in 2025-08-14