

Package leaflet: Information for the user

Caprin 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 Caprin is and what it is used for
2. What you need to know before you take Caprin
3. How to take Caprin
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1. What Caprin is and what it is used for

Caprin 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.

This medicinal product is not recommended for emergencies. It can only be used as a preventive treatment.

Caprin 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).

Caprin 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.

2. What you need to know before you take Caprin

Do not take Caprin if you

- are allergic to acetylsalicylic acid or any of the ingredients in Caprin (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.
- have an acute ulcer in your stomach or small intestine.
- have a history of gastrointestinal bleeding or perforation (gastric or intestinal failure) caused by previous NSAID therapy.
- currently have or have ever had recurrent gastric and duodenal ulcer/haemorrhage with episodes of ulceration or bleeding, 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 and ankle swelling.
- are in the last 3 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 more than 15 mg per week.

Warnings and precautions

Talk to your doctor before taking Caprin

- if you have trouble with your kidneys, liver or heart.
- if you have or have ever had ulcers or bleeding (e.g. in your stomach or small intestine).
- if you have uncontrolled high blood pressure.
- if you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack.
- if you have ever had gout.
- if you have severe menstrual periods.
- if you 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) 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 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.

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

Other medicines and Caprin

Tell your doctor or pharmacist if you are taking or 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 or dissolving (e.g. warfarin, heparin, clopidogrel and alteplase)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics, ACE-inhibitors, angiotensin II receptor agonists and calcium channel blockers)
- 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)
- epilepsy (valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)

- 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)

Caprin with food, drink and alcohol

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

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

Pregnant women should not take acetylsalicylic acid during pregnancy unless advised by their doctor.

If you have taken this medicine while you were pregnant, you must immediately talk to your doctor/midwife so that adequate monitoring can be considered.

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

Pregnancy – last trimester

Do not take Caprin 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 you and your baby's tendency to bleed and cause labour to be later or longer than expected.

If you take Caprin 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 Caprin 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, Caprin 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 your baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

As acetylsalicylic acid is excreted in breast milk, this product should not be taken by patients who are breast feeding unless advised by their doctor.

Fertility

Acetylsalicylic acid may affect female fertility via an effect on ovulation. This effect is reversible after discontinuation of treatment.

Driving and using machines

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

Caprin contains lactose and sunset-yellow

If you have been told that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

This medicine contains sunset-yellow (E110) which may cause allergic reaction.

3. How to take Caprin

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

The recommended dose is 75 mg once daily.

Elderly patients

Recommended dose 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.

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 “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 Caprin 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, pulmonary oedema, coma and shock.

If you forget to take Caprin

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 Caprin

Do not stop taking Caprin without asking your doctor, unless you experience any of the serious side effects listed under “Possible side effects”.

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 Caprin and contact a doctor immediately:

- Swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties (angioedema) (rare).
- Severe skin reaction that appear as 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. Extremely intense and serious skin reactions such as, Stevens-Johnson syndrome have been reported during use of acetylsalicylic acid. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, sores or swelling in the mouth, throat, eyes,

nose and around the genitals and fever flulike symptoms may occur. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences (rare).

- Agranulocytosis. Fever coupled with a severely deteriorated general state of health or a fever in combination with sore throat/mouth or difficulty urinating, which are signs of infection. As acetylsalicylic acid can in rare cases lead to a deteriorated immune system due to a lack of white blood cells, infections can become serious. For this reason, it is also important that you inform health care personnel about your medication (rare).
- Reye's syndrome (a very rare disease in children which affects the brain and liver (see section 2 "Children and adolescents")) (rare).
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools (frequency not known).

Other side effects include:

Common (may affect up to 1 in 10 people)

- Nausea, vomiting, diarrhoea.
- 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 1,000 people)

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- Cramps in the lower respiratory tract, asthma attack.
- Inflammation in the blood vessels.
- Bruising with purple spots (cutaneous bleeding).
- Tender red bumps on the shins.
- Hypersensitivity reactions, such as swelling of e.g. lips, face or body, or anaphylactic shock.
- Abnormal heavy or prolonged menstrual periods.

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

- Anaemia
- Ringing in your ears (tinnitus) or reduced hearing ability.
- Headache.
- Vertigo.
- Ulcers in stomach or small intestine and perforation.
- Prolonged bleeding time.
- Impaired kidney function, acute renal failure.
- Impaired liver function, increased liver enzymes.
- High level of uric acid or low levels of sugar in the blood.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Caprin

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

Do not use Caprin after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Caprin contains

The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 75 mg of acetylsalicylic acid.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, potato starch, talc, triacetin, methacrylic acid-ethylacrylate copolymer (1:1), polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), carminic acid (E120), sunset yellow, aluminium lake (E110).

What Caprin looks like and contents of the pack

Pink, round, biconvex film-coated tablet with a diameter of about 7 mm.

Pack sizes:

Blisters (PVC/Aluminium): 10, 20, 28, 30, 50, 56, 60, 90 and 100 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

Manufacturer

G.L. Pharma GmbH, Schlossplatz 1, A-8502 Lannach, Austria

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

Ireland: Caprin 75 mg gastro-resistant tablets

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