

Package leaflet: Information for the user
Caprin 75 mg Gastro-resistant tablets
aspirin (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, pharmacist or nurse.
- 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, pharmacist or nurse. 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
4. Possible side effects
5. How to store Caprin
6. Contents of the pack and other information

1. What Caprin is and what it is used for

CAPRIN contain the active ingredient acetylsalicylic acid (also called aspirin) which is a non-steroidal anti-inflammatory drug (NSAID).

It is used to:

- prevent blood clots forming (anti-thrombotic)
- reduce the chance of heart attack if you have unstable angina or a stroke or had a previous heart attack (also called “myocardial infarction”)

Caprin are “gastro-resistant” coated tablets so they dissolve after passing through your stomach, preventing irritation. They are good for long-term aspirin treatment. These tablets are NOT for the rapid treatment of pains such as headache as the coating on the tablet releases the drug too slowly.

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 other ingredients of this medicine (listed in section 6)
- if you are allergic to any other NSAIDs (e.g. ibuprofen), seen as a red skin rash, wheezing, asthma, face swelling or runny nose.
- if you have had a cerebral haemorrhage (a type of stroke caused by bleeding in your brain)
- if you have or ever had bleeding or perforation in the stomach or intestines related to aspirin or other non-steroidal anti-inflammatory drugs – NSAIDs (e.g. ibuprofen or naproxen)

- if you currently have or ever had an ulcer in your stomach or gastrointestinal bleeding (two or more episodes)
- if you have severe heart problems (such as severe heart failure which can cause shortness of breath and ankle swelling)
- if you have ever had the problem of your blood not clotting properly or suffer from any bleeding problems
- if you are in the last 3 months of pregnancy, unless advised by your doctor.

Warnings and precautions

Before you take Caprin tell your doctor if you:

- are elderly, you may be more at risk of side effects from NSAIDs. If you notice any problems, **stop taking the tablets and see a doctor immediately**
- are taking other **pain relievers** or **anti-inflammatory** medicines
- have or have ever had gastrointestinal problems such as stomach ulcer, bleeding or black stools
- have inflammatory bowel disease (e.g. Crohn's disease, ulcerative colitis)
- think you may be dehydrated (you may feel thirsty with a dry mouth)
- have trouble with your kidneys or liver
- you have or have had gout
- have heart problems or high blood pressure
- have been told you have a lack of glucose-6-phosphate dehydrogenase (G6PD)
- are asthmatic, aspirin may induce an asthma attack.

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").

Your doctor may monitor you with tests to check your blood, liver, kidney and heart function, especially if you are elderly.

Other precautions

- Medicines such as aspirin may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment, especially if suffering from diabetes, high cholesterol, high blood pressure or if you are a smoker.
- **When given to children aspirin may cause Reye's syndrome. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.**

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

Other medicines and Caprin

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. The effect of treatment may be influenced if aspirin is taken at the same time as some other medicines for:

- thinning of the blood/prevention of clots (e.g. warfarin, heparin)
- organ rejection after transplantation (e.g. ciclosporin, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)

- pain and inflammation (e.g. anti-inflammatory medicines such as ibuprofen, or steroids)
- gout (e.g. probenecid)
- cancer or rheumatoid arthritis (e.g. methotrexate).

These other medicines may also affect or be affected by aspirin:

- insulin or any other drug to treat diabetes (e.g. sulfonylureas such as glibenclamide or tolbutamide)
- corticosteroids (used 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)
- phenytoin or sodium valproate (used to control epilepsy)
- sulphonamides (a type of antibiotic) such as sulfamethoxazole
- medicines such as acetazolamide used to treat glaucoma
- antacids (indigestion medicine). Do not take antacids just before or soon after taking Caprin as they may cause the aspirin to be released too soon
- iron preparations
- antiplatelet drugs (such as clopidogrel and dipyridamole)
- diuretics (water tablets)
- cardiac glycosides (drugs which regulate the heart beat)
- lithium
- aminoglycosides (a group of antibiotics)
- gold, which is sometimes used in rheumatic conditions
- an anaesthetic called thiopental
- selective serotonin re-uptake inhibitors (SSRIs) for depression such as sertraline or paroxetine
- 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 take concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

Before using aspirin, you should inform a healthcare professional about the medicines you are taking. If you are using aspirin regularly you should seek advice before taking any other medicine (including other medicines you may have bought).

Tell your doctor that you are taking aspirin if you are to have a urine test, as it can sometimes interfere with the results.

Taking with food and drink and alcohol

Take the tablets just before food to reduce the risk of side effects.

If you have alcoholic drinks whilst taking Caprin, you may increase the risk of causing bleeding in your stomach or intestines.

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.

Pregnant women should not take aspirin during pregnancy unless advised by their doctor. Regular or high dose aspirin therapy during late pregnancy can cause serious complications in the mother or baby. Do not take Caprin if you are in the last three months of pregnancy.

Do not take Caprin if you are breast-feeding because some of the aspirin may be in your breast milk and could harm your baby.

Do not take Caprin if you are trying to become pregnant as aspirin may reduce female fertility

Driving and using machines

These tablets have no influence on your ability to drive or use machines. However, if you do experience any side effects, do not drive or use machines.

Caprin contains Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Caprin

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

These tablets should be taken for the shortest possible time, at the lowest dose to reduce any side effects. Your doctor may monitor your liver, kidney and heart function.

This medicine should only be taken by mouth, just before food, with liquid. Do not crush or chew.

- **Adults and Elderly:** take 1 tablet once a day. If you have recently had a heart attack, then your doctor may increase the dose to 3 tablets for the first 2 days.
- **Children under 16 years:** this medicine is NOT recommended, unless advised by your doctor.

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 the nearest casualty department. Show any left-over medicines or the empty packet to the doctor.

Common symptoms of an overdose include:

- vomiting
- dehydration
- ringing in the ears
- loss of balance (vertigo)
- deafness
- sweating
- warm hands and feet with a racing pulse
- unusually fast or deep breathing

Less common symptoms of an overdose include:

- vomiting blood

- high fever
- alteration in blood platelets which may lead to an increased risk of bleeding or bruising
- lowering of blood sugar levels (typical early warning signs are feeling hungry, trembling or shakiness and sweating)
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- kidney failure (symptoms include swollen ankles, hands or feet and blood in the urine)
- fluid build-up in the lungs which can cause severe breathlessness.

If you forget to take Caprin

If you miss a dose, take the tablets as soon as you remember unless it is nearly time for your next dose.

Carry on taking the rest of your tablets at the correct time.

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

Caprin may cause hypersensitivity and you must tell your doctor immediately if you experience any of the following:

- skin rashes or itching or swelling of the face, lips, tongue or throat or wheezing or coughing or difficulty breathing.

Side effects may be more serious in elderly patients.

When taking Caprin you may suffer from more serious side effects, **tell your doctor immediately** if you get any of the following:

- signs of intestinal bleeding (bleeding in your stomach or intestines may be fatal), perforation or ulcers such as:
- blood in your vomit
- black stools
- severe stomach pain

other side effects such as:

- heart problems which can cause shortness of breath or ankle swelling
- kidney stones (which can cause severe stomach or back pains)
- bruising with purple spots
- skin rash, skin peeling or blistering (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- blood in your urine
- coughing up blood (however small the amount)
- any swellings

Medicines such as Caprin may be associated with

- a small increased risk of high blood pressure and fluid retention in the body

- a small increased risk of heart attack (also called “myocardial infarction”) or stroke
- asthma and bronchospasm, particularly if you already have asthma.

Aspirin may sometimes cause asthma or bronchospasm (narrowing of the airways that causes wheezing or difficulty breathing).

Aspirin may cause bleeding and you must tell your doctor if you experience any unusual bleeding such as:

- nose bleeds
- signs of bleeding in the brain: severe headache, nausea, vomiting, dizziness, loss of balance, weakness in the limbs.

Other side effects of aspirin include:

- nausea and vomiting
- ringing in your ears
- pain or discomfort in your stomach or lower chest after eating
- diarrhoea
- flatulence
- constipation
- abdominal pain
- indigestion
- high blood pressure
- worsening of colitis, Crohn’s disease or irritation of your colostomy
- recurrent mouth ulcers
- liver problems with symptoms that may include a yellowing of the skin or whites of the eyes (jaundice), dark yellow urine and fatigue.

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 HPRC 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 out of the sight and reach of children. Do not store above 25°C.

Keep the container tightly closed to protect from moisture. Do not use this medicine after the expiry date (EXP) which is stated on the label. The expiry date refers to the last day of that month. Do not throw unused 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 Caprin 75mg contains

- the **active substance** is aspirin (acetylsalicylic acid) (75 mg per tablet)
- the **other ingredients** are: anhydrous lactose (See end of Section 2 for further information on lactose), colloidal silica, pregelatinised starch, zinc stearate, titanium dioxide (E171), polyvinyl acetate phthalate, acetylated vegetable oil monoglyceride, hydroxypropyl cellulose (E463)

black ink: shellac glaze, black iron oxide (E172), n-butyl alcohol, isopropyl alcohol, propylene glycol, ammonium hydroxide.

What Caprin looks like and contents of the pack

Caprin 75 mg are pink, enteric coated round tablets printed with “75” in black ink on one side. They are available in plastic containers containing 20 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

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