

PACKAGE LEAFLET: INFORMATION FOR THE USER

ASPIRIN 75MG GASTRO-RESISTANT TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after three days.

What is in this leaflet:

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

- Aspirin belongs to a group of medicines called antiplatelet agents that help prevent your blood cells sticking together and forming a blood clot.
- Aspirin 75mg Tablets are principally used to prevent blood clots forming following a heart attack or stroke or to help prevent heart attacks and strokes in patients who have previously suffered from these conditions. They may have been prescribed for you if you have recently had by-pass surgery.

2. What you need to know before you take this medicine

Do not take this medicine:

- if you are allergic to any of the ingredients of this medicine (listed in section 6)
- if you have ever had a bad reaction to aspirin or any other non-steroidal anti-inflammatory medicines (you have ever had asthma, swelling of the lips or face, itchy skin or runny nose after taking them)
- if you have, or ever had, an ulcer in your stomach or intestine
- if you are under 16 years old, unless your doctor tells you to
- if you have, or ever had, a bleed in your stomach or intestines (you may have been sick and it contained blood or dark particles that looked like coffee grounds and/or passed blood in your stools or passed black tarry stools)

- if you have had other types of bleeding like a stroke
- if you have a blood clotting disorder (e.g. haemophilia or thrombocytopenia) or are taking medicines to thin your blood
- if you have gout
- if you have severe kidney or liver problems
- if you are in your last 3 months of pregnancy; you must not use higher doses than 100mg per day (see section "Pregnancy and breast-feeding")
- if you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15mg per week.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; aspirin may induce asthma attack
- if you have other kidney, liver or heart problems
- if you have high blood pressure (your doctor may want to monitor you closely)
- if you are dehydrated
- if you have a condition called glucose-6-phosphate dehydrogenase deficiency
- if you are elderly (your doctor may want to monitor you closely)
- if you have or have ever had problems with your stomach or small intestine
- if you 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 Aspirin is blood-thinning there may be an increased risk of bleeding.

Aspirin 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, Aspirin tablets 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 Aspirin 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly the following:

- Warfarin or other blood thinners
- Medicines for depression
- Methotrexate (for cancer, skin problems, rheumatic problems, Crohn's disease)
- Ciclosporin or tacrolimus (given after transplant surgery, or psoriasis or rheumatism)
- Mifepristone (for termination of pregnancy) - do not take this medicine for 8 to 12 days after taking mifepristone
- Other non-steroidal anti-inflammatory medicines, like ibuprofen (to relieve pain, reduce swollen joints, muscles and ligaments)
- Corticosteroids like prednisolone (used for many conditions such as pain, swelling, allergy, asthma, rheumatism and skin problems)
- Phenytoin and sodium valproate (for epilepsy)
- Medicines for diabetes, such as glibenclamide, glipizide (sulphonylureas) or insulin
- Medicines used to treat high blood pressure like ACE inhibitors (e.g. ramipril, captopril)
- Water tablets (diuretics e.g. spironolactone and acetazolamide)
- Metoclopramide (for feeling sick or being sick)
- Probenecid and sulfapyrazone (for gout)
- Lithium (for severe mental problems)
- Medicines for heart problems (e.g. digoxin)
- Sulphonamide antibiotics (e.g. co-trimoxazole)
- Acetazolamide (for glaucoma)
- Zafirlukast (for asthma)
- Antacids (for indigestion) or adsorbents (e.g. kaolin for diarrhoea).

Aspirin may affect the results of thyroid function tests. Tell your doctor or nurse if you are taking these tablets.

Taking this medicine with alcohol

Do **NOT** drink alcohol whilst taking this medicine. Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding

- Ask your doctor or pharmacist for advice before taking any medicine.
- Pregnant women should not take aspirin during pregnancy unless advised by their doctor.
- You should not take Aspirin tablets if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100mg (see section "Do not take this medicine").

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Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

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

Driving and using machines

These tablets do not usually affect the ability to drive or operate machinery.

3. How to take this medicine

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has advised you. You should check with your doctor or pharmacist if you are not sure.
- Swallow the tablet(s) with a small glass of water and do not cut, chew or crush it.
- Do not take any medications for indigestion either immediately before or after taking this medicine.

Dosage:

Adults, elderly and children of 16 years and over: Take one or two tablets once daily.

In some circumstances a higher dose may be appropriate, especially in the short term, and up to 4 tablets daily may be used on the advice of a doctor.

Caution is required in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Do not give to children aged under 16 years unless on the advice of doctor. There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal.

DO NOT EXCEED THE STATED DOSE

If you take more number of tablets than you should

Contact your nearest hospital casualty (A&E) or your doctor immediately. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

If you forget to take a dose

If you forget to take a dose, skip the dose and take the next dose as usual.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE.

4. Possible Side Effects

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

STOP TAKING this medicine and tell your doctor immediately if you suffer from any of the following:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction), shock

- 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 a stroke due to bleeding in brain 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 nose
- 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
- Inflammation of the stomach lining
- Nausea and vomiting
- Cramps in the lower respiratory tract, asthma attack
- Inflammation in the blood vessels
- Abnormal heavy or prolonged menstrual periods

Not known: 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
- Diarrhoea
- Increased bleeding time, e.g. when you have a nose bleed, bleeding gums (if bleeding is severe or lasts for a long time, talk to your doctor straight away)
- Impaired kidney function
- Salt and water retention
- Impaired liver function
- High level of uric acid in the blood
- Anaemia (a reduction in the number of red blood cells which can make you look pale and feel tired) may occur due to bleeding

- Kidney stones (sharp stabbing pains in the stomach or back, with blood in the urine)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

- Keep this medicine out of the sight and reach of children.
- Do not take your tablets after the expiry date marked on the pack after (EXP). The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- 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 this medicine contains

- Each gastro- resistant tablet contains aspirin 75mg, as the active ingredient.
- The other ingredients are: potato starch, calcium hydrogen phosphate dihydrate E341, microcrystalline cellulose E460, talc E553b, methacrylic acid – ethylacrylate-copolymer (containing sodium lauril sulfate and polysorbate 80), macrogol, simeticone.

What this medicine looks like and contents of the pack

- These tablets are white, circular, plain on both faces.
- This medicine is available in blister packs of 28, 32, 56 or 84 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
Unit 3, Canal side, Northbridge Road, Berkhamsted, Hertfordshire, United Kingdom, HP4 1EG

Telephone: 0044 (0)1442 200922

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Aspirin 75mg Gastro-resistant Tablets; PL 17907/0157, PL 17907/0158

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To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, fax, email) above.

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430 mm

Aspirin 75 mg Tablets
Insert

SAME SIZE ARTWORK
430 x 128 mm
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