FLAT DIMENSION = 130 x 560mm

FOLDED DIMENSION
With single fold = 130 x 280mm
With 4 folds = 130 x 35mm

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**PACKAGE LEAFLET:**
**INFORMATION FOR THE USER**

# ASPIRIN 75MG GASTRO-RESISTANT TABLETS (acetylsalicylic acid)

**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, pharmacist or nurse 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, pharmacist or nurse. 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.

**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 aspirin or any of the other ingredients of this medicine (listed in section 6).
- are allergic to other salicylates or nonsteroidal 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
- if you have, or ever had, an ulcer in your stomach or intestine
- 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
- have ever had gout

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.

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).

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.

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

**The effects of treatment may be influenced if aspirin is taken at the same time as other medicines for:**
- Thinning of the blood/prevention of clots (e.g. warfarin, heparin, phenindione and clopidogrel)
- Medicines for depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine)
- Methotrexate (for cancer, skin problems, rheumatic problems, Crohn's disease)
- Ciclosporin or tacrolimus (given after transplant surgery, or psoriasis or rheumatism)
- Other non-steroidal anti-inflammatory medicines, like ibuprofen, or steroids (to relieve pain, reduce swollen joints, muscles and ligaments)
- 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).
- Phenytoin and sodium valproate (for epilepsy)
- Medicines for diabetes, such as gliben clamide, 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)
- Probenecid and sulfinpyrazone (for gout)
- Lithium (for severe mental problems)
- Iron salts (for treatment of iron deficiency anaemia), carbonates (treatment of peptic ulcer and reflux), Alkali hydroxides (antacids)
- Medicines for heart problems (e.g. digoxin)
- Acetazolamide (for glaucoma)
- 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 aspirin for cardio protection.

Before taking 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 medicine you may have bought).

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

**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**
If you continue or start treatment with acetylsalicylic acid during pregnancy per instruction of the physician, then use acetylsalicylic acid as advised by your doctor and do not use a higher dose than is recommended.
**Pregnancy - last trimester**
Do not take acetylsalicylic acid 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 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 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 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**
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, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse 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.

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**Dosage:**
**Adults, elderly and children of 16 years and over:** Take one or two tablets once daily.
The usual dose for the long-term management of cardiovascular disease (disease affecting the blood supply to the heart) or cerebrovascular disease (disease affecting the blood supply to the brain) or following by-pass surgery is 1 to 2 tablets, once a day.
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 Aspirin 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 left-over 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 Aspirin**
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 dose.
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.

**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
- 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 e.g. lips, face or body, or shock

**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)
- 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, 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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$^{0}$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**
Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire,
United Kingdom, HP4 1EG
Telephone: 0044 (0)1442 200922
E-mail: info@bristol-labs.co.uk

**Manufacturer**
**Bristol Laboratories Limited**
Laporte Way, Luton, LU4 8WL,
United Kingdom

**Bristol Laboratories Limited**
Unit 5, Traynor Way,
Whitehouse Business Park,
Peterlee, SR8 2RU,
United Kingdom

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

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