

## 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 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 any of the 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.

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 (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 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)
- Probenecid and sulfapyrazone (for gout)
- Lithium (for severe mental problems)
- 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 cardioprotection.

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).

**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"). 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.

xxxxxxx

### 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.

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 number of tablets 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 a dose

If you miss a dose, wait until it is time for your next dose, then go on as normal. If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 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
- Bruising with purple spots (cutaneous bleeding)

**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](http://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°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

Fax: 0044 (0)1442 873717

E-mail: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

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

**This leaflet was last revised in February 2020.**

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.

V11 19-02-20 D0

Aspirin 75 mg Tablets  
Insert

SAME SIZE ARTWORK  
430 x 130 mm  
Back

430 mm

XXXX

Artwork originator; eSign & Date:	Artwork Checker; eSign & Date:	Approved for Regulatory submission; eSign & Date:	Final approval by MA Holder confirming receipt regulatory approval; eSign & Date	Packing Site Approval; eSign & Date:
Kaypee Design kaypeedesign@gmail.com			APPROVED By namita at 10:01 am, Mar 12, 2020	

Artist's artwork version with/without date	V1 14-04-2015 D0, V2 15-04-2015 D1, V3 17-04-2015 D0, V4 03-06-2015 D0, V5 04-06-2015 D0, V6 28-07-2015 D0, V7 18-11-2016 D2, V8 23-11-2016 D0, V9 16-12-19 D0, V10 17-12-19 D0, V11 19-02-20 D0
MA Number (s)	PL 17907/0157 & PL 17907/0158
MA Holder	Bristol Laboratories Ltd.
Packaging site	
Reason for revision	Text changed
Dimensions:	L: 430 mm W: 130 mm D:
Fonts & size	Arial Narrow Text size -7.8, Sub headings size-9, Main Heading size-10
Pantone colours	Black
Manufacturing site	Name: Manufacturing site code if applicable:
<p>IMPORTANT: Artwork, text and content must not be reset, remade, amended or altered. The only exceptions to this are: bleeds, chokes, spreads or other print related adjustments required for reproduction by the supplier. We must receive a copy of any 3rd Party Supplier's Proof before approval to print will be granted.</p>	