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Package Leaflet: Information for the user

**DISPERSIBLE ASPIRIN 75MG TABLETS
acetylsalicylic acid**

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

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

- Keep this leaflet. You may need to read again.
- If you have any further questions, ask your doctor, or 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, 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 Aspirin is and what it is used for**
- 2.What you need to know before you take Aspirin**
- 3.How to take Aspirin**
- 4.Possible side effects**
- 5.How to store Aspirin**
- 6.Contents of the pack and other information**

1. What Aspirin is and what it is used for

- Each tablet contains the active ingredient Aspirin 75 mg of medicines called antiplatelet agents that help prevent your blood cells sticking together and forming a blood clot
- Aspirin 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 Aspirin

Do not take this medicine if you:

- are **allergic to acetylsalicylic acid** or any of the ingredients in this medicine (see 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
- currently have or have ever had an **ulcer** in your stomach or small intestine, indigestion problems or any other type of bleeding like a **stroke**
- have a **blood clotting disorder** (e.g.haemophilia or thrombocytopenia) or are taking medicines to thin your blood

- are suffering from **gout**
- have **severe liver** or **kidney** problems
- are in your last 3 months of **pregnancy**; you must not use doses higher than 100mg per day (see section “Pregnancy, breast-feeding and fertility”)
- 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, pharmacist or nurse before using these tablets if you:

- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have **higher** blood pressure
- are **asthmatic**, have hay fever, nasal polyps or other chronic respiratory
- diseases; acetylsalicylic acid may induce an asthma attack
- have ever had gout
- 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 acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

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, Aspirin 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 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.

Other Medicines and Aspirin

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines without a prescription.

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, coumarin, dipyridamole heparin, phenindione and clopidogrel)
- Organ rejection after transplantation (e.g. ciclosporin, tacrolimus)
- High blood pressure (e.g. diuretics and ACE-inhibitors)
- Regulation of the heart beat (digoxin)
- Manic-depressive illness (lithium)
- Pain and inflammation (e.g. anti-inflammatory medicines such as ibuprofen, or steroids)
- Gout (e.g. probenecid)
- Epilepsy (valproate, phenytoin)
- Glaucoma (acetazolamide)
- Cancer or rheumatoid arthritis (e.g. methotrexate)

- Diabetes (e.g. glibenclamide)
- 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)
- Iron salts (for treatment of iron deficiency anaemia), carbonates (treatment of peptic ulcer and reflux), Alkali hydroxides (antacids), adsorbents (e.g. kaolin for diarrhoea)
- Alcohol may increase the risk of side effects. Avoid alcohol whilst taking Aspirin
- 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 with food, drink and alcohol

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.

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

Pregnancy - last trimester Do not take Aspirin 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 Aspirin 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 Aspirin 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, Aspirin 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 acetylsalicylic acid unless advised by their doctor.

Driving and using machines

Aspirin does not usually affect the ability to drive or operate machinery.

Aspirin Tablets Contains Lactose

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

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3. How to take Aspirin

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will have decided the right dose of Aspirin for you so follow his or her instructions. These tablets are suitable for adults, the elderly and young people 16 years and over.

- Stir the tablets in a small glass of water until dispersed and drink immediately
- 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.

In general, acetylsalicylic acids (such as aspirin) should be used with caution in elderly who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Aspirin is not intended for children under 16 years of age. There is a risk of Reye's syndrome when aspirin is taken by children. Reye's syndrome is a very rare disease that can be fatal.

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 tablet. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you take more Aspirin than you should: If you or someone else accidentally takes too many tablets, tell your doctor at once. If you cannot do this, go to the nearest hospital 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.

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

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 Aspirin and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction)
- 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
- Ulcers in stomach or small intestine and perforation
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools
- Severe bleeding in the stomach and in testines.
- Cramps in the lower respiratory tract, asthma attack
- Bleeding in the brain

Common side effects (may affect up to 1 in 10 people):

- Indigestion

- Increased tendency for bleeding

Uncommon side effects (may affect up to 1 in 100 people):

- Hives or urticaria (rash)
- Runny noses
- Breathing difficulty

Rare side effects (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
- Hypersensitivity reactions, such as swelling of e.g. lips, face or body, or shock
- Changes in blood cell numbers symptoms include unexplained bruising and bleeding, infections, tiredness, fever, sore throat, mouth ulcers
- Nausea and vomiting
- Inflammation in the blood vessels
- Bruising with purple spots (cutaneous bleeding)
- Abnormal heavy or prolonged menstrual periods
- Severe skin reactions such as rash known as 'erythema multiforme' and its life threatening forms: Stevens-Johnson syndrome and Lyell's syndrome

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

- Ringing in your ears (tinnitus) or reduced hearing ability
- Headache
- Vertigo (spinning sensation)
- Ulcers in stomach or small intestine and perforation
- Diarrhoea
- Prolonged bleeding time
- Impaired kidney function
- Salt and water retention
- Impaired liver function
- High level of uric acid 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 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 Aspirin

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package Containers: Keep the container tightly closed.

- Do not use this medicine after the expiry date which is stated on the carton.
- 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 Aspirin Tablets contain

- Each tablet contains Aspirin 75mg, as the active ingredient
- The other ingredients are: sodium saccharin, citric acid, calcium carbonate, maize starch, purified talc, sodium lauryl sulfate, lactose monohydrate.

What the tablets look like and contents of the pack

- Tablets are white and flat debossed <F> on one side and plain on the other.
- The blisters are available in packs of 12, 20, 24, 28, 30, 32, 48, 56, 60, 84, 96, 98 and 100 tablets.
- The containers are available in packs of 32, 50, and 100 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
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Telephone: 0044 (0)1442 200922
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Dispersible Aspirin 75mg Tablets; PL 17907/0155

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