

PATIENT INFORMATION LEAFLET

Aspirin 75mg Tablets

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Aspirin 75mg Tablets are and what they are used for

- Each tablet contains the active ingredient Aspirin 75 mg.
- Aspirin (acetylsalicylic acid) 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. Before you take Aspirin 75mg Tablets Do not take this medicine if you:

- are allergic to acetylsalicylic acid or any of the ingredients in Aspirin tablets (see section 6 "Further information")
- 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 or any other type of bleeding like a stroke
- have ever had the problem of your blood not clotting properly
- are suffering from gout
- have severe liver or kidney problems
- are in your last 3 months of pregnancy; you must not use higher doses than 100mg per day (see section "Pregnancy and breast-feeding")
- are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15mg per week.

Take special care with this medicine

Before you take Aspirin tablets tell your doctor if you:

- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have high 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 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 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.

Aspirin tablets contain lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken 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, 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)
- 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 Aspirin tablets with food and drink:

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'). 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 acetylsalicylic acid unless advised by their doctor.

Driving and using machines

Aspirin tablets should not affect your ability to drive and use machines.

Important information about some of the ingredients of Aspirin Tablets:

These tablets contain the colourant sunset yellow (E110). This can cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

3. How to take Aspirin 75mg Tablets

Your doctor will have decided the right dose of Aspirin Tablets for you so follow his or her instructions. These tablets are suitable for adults, the elderly and young people over 16 years of age. They should be taken orally with a drink of water.

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 patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Aspirin 75mg Tablets 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 take more Aspirin 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 Aspirin tablets

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.

4. Possible side effects

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

If you notice any of the following serious side effects, stop taking Aspirin tablets 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
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools.

Common side effects (may occur in 1 to 10 out of 100 patients):

- Indigestion
- Increased tendency for bleeding.

Uncommon side effects (may occur in 1 to 10 out of 1,000 patients):

- Hives
- Runny noses
- Breathing difficulty.

Rare side effects (may occur in 1 to 10 out of 10,000 patients):

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells
- Nausea and vomiting
- Cramps in the lower respiratory tract, asthma attack
- Inflammation in the blood vessels
- 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
- Abnormal heavy or prolonged menstrual periods.

Side effects with unknown frequency

- Ringing in your ears (tinnitus) or reduced hearing ability
- Headache
- Vertigo
- 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, 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 Aspirin 75mg Tablets

- Store in a dry place below 25°C.
- Do not use after the expiry date shown on the package.
- Keep out of the reach and sight of children.

6. Further Information

What Aspirin 75mg Tablets contain

Each tablet contains the active ingredient Aspirin 75 mg. The tablets also contain Lactose, Starch, Sucrose, Orange Oil, Saccharin, Talc and permitted colour (Sunset Yellow, E110).

What Aspirin 75mg Tablets look like and contents of the pack

Each pack contains 28, 50 or 1000 round orange tablets with a breakline on one face. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Intrapharm Laboratories Ltd,
The Courtyard Barns,
Choke Lane,
Cookham Dean,
Maidenhead,
Berks SL6 6PT.

Manufacturer and EU site for batch release:

Surepharm Services Ltd,
Bretby Business Park, Bretby,
Burton-on-Trent, Derbyshire. DE15 0YZ

This leaflet does not include all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. If you have any medicine left over at the end of your treatment, please return this to your pharmacy who will dispose of it safely.

This leaflet was last revised in March 2020.