

Package Leaflet: Information for the user

DISPERSIBLE ASPIRIN TABLETS 75mg

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 doctor or 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.

What is in this leaflet

1. What Dispersible Aspirin Tablets 75 mg are and what they are used for
2. What you need to know before you take Dispersible Aspirin Tablets 75 mg
3. How to take Dispersible Aspirin Tablets 75 mg
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6. Contents of the pack and other information

1. WHAT DISPERSIBLE ASPIRIN TABLETS 75mg ARE AND WHAT THEY ARE USED FOR

Aspirin is an antiplatelet agent that helps prevent your blood cells sticking together and forming a blood clot. Dispersible Aspirin Tablets 75mg are used to prevent further heart attacks and strokes in patients with a previous history of heart attacks, unstable angina or stroke, and following by-pass surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DISPERSIBLE ASPIRIN TABLETS 75mg

Do NOT take these tablets if:

- you are allergic (hypersensitive) to aspirin, other salicylates or any of the other ingredients of this medicine (listed in section 6)
- you 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
- you have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding or stroke.
- you suffer from gout or have a history of gout
- you suffer from haemophilia or any other blood clotting disorder
- you are taking medicines to prevent blood clotting (e.g. warfarin, heparin or acenocoumarol)
- you are in the last stages of pregnancy or are breast feeding
- you have severe liver or kidney problems
- you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.

Do not take with any other aspirin-containing products.

Warnings and precautions

Tell your doctor or pharmacist before you take this medicine if you:

- have asthma or suffer from any allergies
- have trouble with your liver, kidneys or heart
- have or have ever had problems with your stomach or small intestine
- have high blood pressure
- have ever had gout
- have heavy menstrual periods
- are suffering from dehydration.

There is a possible association between aspirin and Reye's Syndrome when given to children with a fever. Reye's syndrome is a very rare disease which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor (e.g. for Kawasaki's disease).

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.

This medicine is not suitable as a painkiller or fever reducer.

Other medicines and Dispersible Aspirin Tablets 75 mg

Talk to your doctor or pharmacist if you are taking any of the following as they may affect your treatment:

- medicines to reduce clotting/thinning of the blood e.g. warfarin, heparin, clopidogrel or ticlopidine
- 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)
- medicines that might cause stomach irritation e.g. NSAIDs (non steroidal anti-inflammatory drugs)
- medicines for pain or inflammation e.g. steroids or anti-inflammatory medicines
- spironolactone (a diuretic/water tablet)
- methotrexate (for psoriasis, arthritis or tumours)
- probenecid or sulfapyrazone (for gout)
- acetazolamide (for glaucoma)
- metoclopramide (for sickness or digestive disorders)
- epilepsy (valproate, phenytoin)
- 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 (for indigestion)

If you are using aspirin regularly seek advice of your doctor before taking any other medicines, including medicines obtained without a prescription.

Dispersible Aspirin Tablets 75 mg 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 Dispersible 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 100 mg.

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

Breastfeeding women should not take aspirin unless advised by their doctor.

Driving and using machines

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

Dispersible Aspirin Tablets 75 mg contain lactose

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

3. HOW TO TAKE DISPERSIBLE ASPIRIN TABLETS 75mg

See your doctor before taking this medicine for the first time.

Disperse the tablets in a glass of water. You must drink the whole glass of fluid to receive the correct dose.

Adults

Take 1-2 tablets a day. In some cases your doctor may advise you to take up to four tablets a day, especially in the short-term. Follow your doctor's instructions.

- If symptoms persist consult your doctor.

Do not give to children under 16 years of age unless advised by 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.

If you forget to take a tablet take one as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose. Take the next dose at the correct time.

If you take more tablets than you should or if you think a child has swallowed any of the tablets, contact your doctor or nearest hospital casualty department immediately. Please take this leaflet, any remaining tablets and the container with you.

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

STOP taking the tablets and contact your doctor immediately if you experience any of the following:

- An asthma attack or other allergic reaction, such as wheezing or difficulty breathing, skin rashes or itching, swelling of the lips, tongue or face, fainting or difficulty 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.
- Stomach ulcer irritation or bleeding (symptoms may include stomach pain, vomiting of blood, passing black tarry-looking stools).
- Reduction in the number of blood platelets which increases the tendency to bleed and bruise more easily.

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 (a bleed in the brain which can cause sudden severe headache, fit or stroke); 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 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 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 DISPERSIBLE ASPIRIN TABLETS 75mg

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in a dry place in the original package.

Do not use after the expiry date printed on the pack. The expiry date refers to the last day of that month. 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 these tablets contain:

- The active ingredient in each tablet is aspirin 75mg.
- The other ingredients are calcium carbonate, starch, lactose, citric acid anhydrous, talc, sodium saccharin and sodium lauryl sulphate.

What these tablets look like and contents of the pack:

The tablets are white, flat and round with 'ASP' and '75' on one side, and plain on the other.

They are available in blister packs of 10, 14, 16, 20, 24, 28, 30, 32, 40, 42, 50, 56, 60, 70, 80, 84, 90, 98 and 100 tablets. Plastic containers of 25, 50, 100 and 1,000 tablets are also available.

Marketing Authorisation Holder and Manufacturer: M & A Pharmachem Ltd, Bolton BL5 2AL, UK.

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