

Aspirin 300mg tablets

acetylsalicylic acid

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Aspirin 300mg tablets but within this leaflet it will be referred to as Aspirin tablets.

What is in this leaflet

- 1 What Aspirin tablets are and what they are used for
- 2 What you need to know before you take Aspirin tablets
- 3 How to take Aspirin tablets
- 4 Possible side effects
- 5 How to store Aspirin tablets
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1 What Aspirin tablets are and what they are used for

Aspirin tablets belong to a group of medicines which have analgesic (pain relieving), anti-inflammatory (inflammation reducing) and antipyretic (temperature reducing) properties.

These tablets may be used for the relief of:

- headache, toothache, migraine, neuralgia (nerve pain), sore throat or period pains.
- symptoms of influenza, feverishness, rheumatic pains (pain, stiffness and discomfort of the joints), sciatica (nerve pain of the leg/back), lumbago (lower back pain), fibrositis (muscular rheumatism), muscular aches and pains.

The tablets may also be used to prevent blood clots especially after a heart attack or in patients with unstable angina or reduced blood flow in the brain.

2 What you need to know before you take Aspirin tablets

Do not take Aspirin tablets and tell your doctor if you:

- are **allergic to aspirin, salicylates or non-steroidal anti-inflammatory drugs** (NSAIDs), or other ingredients of this medicine. You may have developed difficulty breathing, a runny nose, itchy skin or swelling after taking aspirin or a NSAID previously (see section 6)
- have a **stomach ulcer** or a history of ulcers or **indigestion**
- have **nasal polyps** associated with **asthma**
- have **haemophilia** or other **blood clotting** disorders or are taking medicines to thin the blood
- have severe **liver** or severe **kidney** problems or severe **heart failure**
- are in the last 3 months of **pregnancy**
- are a child **under 16** years old
- are taking **methotrexate** (15mg a week).

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Warnings and precautions

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. 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.

Taking a **painkiller** for **headaches** too often or for too long can make them worse.

Talk to your doctor or pharmacist before taking Aspirin tablets if you:

- have **asthma** or **allergies**
- have **heart, liver or kidney** problems or **gout**
- have an **overactive thyroid** gland
- are **dehydrated** (you may feel thirsty and have a headache, dry mouth and lips)
- have **anaemia** or suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (**G6PD**); this can cause episodes of anaemia after eating certain foods such as fava beans (favism)
- have systemic lupus erythematosus (**SLE**) or other connective tissue disease
- are **elderly**
- have had any disorders affecting blood vessels in the **brain**
- have received a **varicella (chickenpox) vaccination** within the last 6 weeks
- are planning to become **pregnant**
- have **heavy bleeding** during your periods
- have a history of **stomach ulcers**
- have **chronic respiratory disease**
- have **hypertension**
- are taking **deferasirox** (a medicine to remove excess iron from the body).

Other medicines and Aspirin tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- warfarin, coumarin, heparin, dipyridamole and clopidogrel (used to prevent blood clotting)
- metoclopramide or domperidone (to prevent sickness)
- diuretics ("water tablets") such as spironolactone, furosemide, acetazolamide (to treat high blood pressure)
- medicines which make your urine more alkaline such as antacids, citrates
- probenecid (to treat gout)
- methotrexate (to treat some cancers, psoriasis and rheumatic disease)
- sulfonylureas (antidiabetics)
- phenytoin or sodium valproate (to treat epilepsy)
- corticosteroids (to suppress the immune system)
- mifepristone (to induce abortion)
- other non-steroidal anti-inflammatory drugs - NSAIDs (such as ibuprofen or naproxen)
- metanzolone (substance to decrease pain and fever) may reduce the effect of aspirin on platelet aggregation (blood cells sticking together and forming a blood clot), when taken at the same time. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection
- vancomycin (medicines which can cause hearing problems)
- medicines to treat high blood pressure such as ACE inhibitors (e.g. enalapril, lisinopril, perindopril), Calcium channel blockers (e.g. amlodipine, diltiazem, nifedipine)
- SSRIs such as sertraline or paroxetine (medicines to treat depression)
- varicella (chickenpox) vaccine. Aspirin should be avoided for 6 weeks after vaccination

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- herbal medicines containing ginkgo biloba
- digoxin (to treat heart problems)
- lithium (to treat depression)
- acetazolamide (to treat glaucoma)
- cyclosporin, tacrolimus (used to prevent organ rejection)
- alcohol.

Pregnancy and breast-feeding

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. Avoid taking Aspirin tablets during pregnancy, especially in the last 3 months of pregnancy or whilst breast-feeding.

Surgery and tests

If you need to have an operation including having your teeth removed or blood and urine tests, tell your doctor or dentist you are taking this medicine.

3 How to take Aspirin tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Avoid alcohol whilst taking this medicine.

Swallow the tablets with a **glass of water**.

Doses:

Adults, including the elderly:

The recommended dose is 1 or 2 tablets every 3 to 4 hours as required. No more than 12 tablets in any 24 hour period.

For prevention of blood clots:

The recommended dose is 1 tablet once a day.

Use in children and adolescents

Aspirin tablets are not recommended for use in children and adolescents younger than 16 years

If you take more Aspirin tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include ringing in the ears, spinning sensation, fast breathing rate, changes in some of the chemicals in the body, heart failure, changes in body temperature resulting in dehydration, restlessness, fits, hallucination (seeing or hearing things that are not there), headache, hearing problems, confusion, feeling or being sick, stomach pain or coma.

If you forget to take Aspirin tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Do not take more than one dose in any 4 hour period.

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

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 tablets and contact a doctor immediately:

- Difficulty breathing
- Severe allergic reactions (blistered skin, swelling of the face, lips, throat or tongue, difficulty breathing, worsening of asthma, shock)
- Severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (Lyell's syndrome) or severe rash, blisters, or red patches on the skin (Stevens-Johnson syndrome)
- Bleeding on the brain (sudden severe headache, fit, changes in vision, speaking, understanding or coordination, weakness in an arm or leg)
- Stomach ulcers or bleeding which can be severe (you may develop bloody or black tarry stools, severe stomach pain and vomit blood), stomach irritation (mild stomach pain, heartburn and feeling or being sick) and inflammation of the liver
- Salicylism - if you take large doses for a long time you may develop symptoms of salicylism, these include: dizziness, ringing or buzzing in the ear, deafness, sweating, feeling or being sick, headache and confusion
- Hepatitis (inflammation of the liver causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles).

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Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common: may affect up to 1 in 10 people

- Increase in the number of nose bleeds, longer bleeding time or notice that you bruise more easily or have more infections talk to your doctor
- Indigestion.

Uncommon: may affect up to 1 in 100 people

- Runny nose
- Itchy skin rash caused by allergic reaction- pale or red irregular raised patches with severe itching (hives).

Rare: may affect up to 1 in 1,000 people

- Anaemia, changes in numbers and types of blood cells and enzymes seen in blood tests
- Difficulty breathing or wheezing, worsening of asthma
- Heavy periods
- Irregular red patches on the skin of the hands and arms (erythema multiforme)
- Disorder characterised by blood spots, bruising and discolouring to skin (Purpura)
- Bleeding in the skin, mucous membranes
- Red tender lumps developing under the skin (Erythema nodosum).

Not known: frequency cannot be estimated from the available data

- Gout (high levels of uric acid in the blood)- causing crystals to deposit in joints of hands/feet causing pain (Hyperuricaemia)
- Nosebleeds; bleeding of the gums, which may be prolonged. (Please advise doctor or dentist if surgery is planned)
- Reduction of red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia). Reduction in red blood cells which cause pale yellow skin and weakness or breathlessness (haemolytic anaemia), blood disorder resulting in impaired blood clotting leading to an increased risk of bleeding, reduced number in red and white blood cells, blood loss, elevated blood enzymes levels (as seen in blood test)
- Headache
- Feeling of dizziness or spinning
- Hearing loss; ringing or buzzing in the ears
- Liver problems
- Reduced kidney function.

Additional side effects in children

Aspirin may be associated with the development of a condition called Reye's Syndrome, which causes severe liver and brain damage.

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 Aspirin tablets

Keep this medicine out of the sight and reach of children Store the tablets below 25°C in a dry place.

Do not use Aspirin tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Aspirin tablets contain

- The active substance (the ingredient that makes the tablets work) is 300mg aspirin (also known as acetylsalicylic acid).
- The other ingredients are maize starch, talc (E553(b)).

What Aspirin tablets look like and contents of the pack

Aspirin tablets are white, circular, biconvex uncoated tablets marked "ASPIRIN 300mg" on one face and the letters "C" and "AO" on either side of a central division line on the reverse. Alternatively, the reverse is blank.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK.

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