

FLAT DIMENSION = 130 x 560mm
FOLDED DIMENSION = 130 x 35mm

30 MM

8 MM

PACKAGE LEAFLET: INFORMATION FOR THE USER

ASPIRIN 300MG TABLETS
acetylsalicylic acid

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, pharmacist or nurse 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, 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

- Aspirin belongs to a class of medicines called non-steroidal anti-inflammatory drugs. It has analgesic (pain relieving), antipyretic (temperature reducing) and anti-inflammatory (inflammation reducing) properties.
- It is used for the relief of mild to moderate pain, including headache, migraine, neuralgia (nerve pain), toothache, sore throat, period pains, aches and pains and for relief of influenza, feverishness and feverish colds.
- It is also used for the relief of sprains, strains, rheumatic pain, sciatica (nerve pain of the leg/back), lumbago (lower back pain), fibrositis (muscular rheumatism), muscular aches and pains, joint swelling and stiffness.

2. What you need to know before you take Aspirin

Do not take these tablets if you:

- are allergic to aspirin, salicylates or any other non-steroidal anti-inflammatory drugs, such as Ibuprofen. You may have developed difficulty breathing, runny nose, rash, or swollen face or lips, after taking aspirin or a NSAID previously.
- are allergic to any of the other ingredients in the tablet (listed in section 6)
- have been told you suffer from haemophilia or from any disease which affects the clotting of your blood
- are taking medicines to thin your blood such as Warfarin
- are under 16 years old, unless your doctor has told you to take aspirin
- have had an asthma attack after taking Aspirin

- have gout
- have a stomach ulcer or a history of stomach or indigestion
- Nasal polyps associated with asthma
- severe liver or severe kidney problems or severe heart failure
- If you are in the last three months of your pregnancy, you must not use higher doses than 100 mg per day (see section "Pregnancy, breast-feeding and fertility").
- taking methotrexate (15mg a week)

Important warning:

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.

Warnings and precautions

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

- suffer from asthma or other allergies
- are dehydrated (you may feel thirsty and have a headache, dry mouth and lips)
- have heart, liver or kidney problems
- are elderly
- 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
- 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 or chronic diseases
- have hypertension or diabetes
- are taking deferasirox (a medicine to remove excess iron from the body)
- have an overactive thyroid gland
- severe skin rash (steven-Johnsons syndrome)
- increased clotting time
- have risk of bleeding

Other medicines and Aspirin

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

- medicines which make your urine more alkaline such as antacids, citrates
- Mifepristone (for termination of pregnancy)- do not take this medicine for 8 to 12 days after taking mifepristone

- Other non-steroidal anti-inflammatory drugs, NSAIDs (such as ibuprofen or naproxen)
- warfarin, coumarin, heparin, dipyridamole and clopidogrel (used to prevent blood clotting)
- Medicines for epilepsy (e.g. Phenytoin and Sodium Valproate)
- Medicines to treat gout (e.g. Probenecid and Sulphinpyrazone)
- Methotrexate (to treat some cancers, psoriasis and rheumatic disease)
- Corticosteroids (to suppress the immune system)
- medicines to treat high blood pressure such as ACE inhibitors (e.g. enalapril, lisinopril, perindopril), calcium channel blockers (e.g amlodipine, diltiazem, nifedipine)
- Zafirlukast (for asthma),
- Metoclopramide or domperidone (to prevent sickness)
- diuretics ("water tablets") such as spirinolactone, furosemide, acetazolamide (to treat high blood pressure)
- sulphonylureas (antidiabetics), insulin (hypoglycaemics)
- Alcohol may increase the risk of side effect
- Vancomycin (medicines which can cause hearing problems)
- SSRIs such as sertraline or paroxetine (medicines to treat depression)
- Varicella (chickenpox) vaccine. Aspirin should be avoided for 6 weeks after vaccination.
- herbal medicines containing ginkgo biloba
- digoxin (to treat heart problems)
- lithium (to treat depression)
- acetazolamide (to treat glaucoma)
- cyclosporine, tacrolimus (used to prevent organ rejection)
- 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.

Aspirin Tablets 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

SAME SIZE ARTWORK
560 x 130 MM

Front

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.

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.

Driving and using machines

These tablets do not usually affect the ability to drive or operate machinery.

Aspirin Tablets contain Lactose

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

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.

- Swallow the tablet(s) with a glass of water and do not cut, chew or crush the tablets.

The recommended dose is:

Adults, including the elderly: 1 or 2 tablets every 3 to 4 hours as required. No more than 12 tablets in any 24 hour period.

Do not give to children aged under 16 years, unless on the advice of a doctor (see under 'important warning' in section 2).

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 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 the 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, pharmacist or nurse.

4. Possible Side Effects

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

Stop taking this medicine and contact a doctor immediately if you have any of the following:

- 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 (Lyells syndrome) or severe rash, blisters, or red patches on the skin (Stevens-Johnson syndrome)

- Bleeding on the brain (sudden severe headache, fits, 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 stomach (gastritis)
- 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)

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)
- Shortness of breath

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 or mucous membranes
- Red tender lumps developing under the skin (Erythema nodosum)

Not known: frequency cannot be estimated from the available data

- Hyperuricemia (high levels of uric acid in the blood)- causing crystals to deposit in joints of hands/feet causing pain (gout)
- 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, urate kidney stones

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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store this medicine 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 Aspirin tablets contain

- Each tablet contains Aspirin 300mg, as the active ingredient
- The other ingredients are starch, lactose monohydrate and purified talc (E553b)

What the tablets look like and contents of the pack

- Aspirin 300mg tablets are white, biconvex which have breakline on one side and debossed <A> on other side
- The blister packs are available in packs of 8, 10, 12 or 16 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Aspirin 300mg Tablets; PL 17907/0152

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