

Package Leaflet: Information for the User

ASPIRIN 300mg Effervescent Tablets

Acetylsalicylic acid (Aspirin)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription.

However, you still need to use Aspirin carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

IN THIS LEAFLET:

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1. WHAT IS ASPIRIN AND WHAT IS IT USED FOR?

Each effervescent tablet contains aspirin (acetylsalicylic acid). They dissolve in water to form a sparkling, lemon-tasting solution which is absorbed quickly into the bloodstream.

Aspirin belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It is used for the treatment of pain and reduction of fever and also has anti-inflammatory properties.

Aspirin can be used for the:

- Treatment of mild to moderate pain including headache, migraine, toothache, period pains, sore throat, nerve pain (neuralgia), aches and pains.
- Symptomatic relief of influenza, feverishness, colds, backache (lumbago), sciatica, fibrositis, rheumatic pain (arthritis), muscular aches and pains.

2. BEFORE YOU TAKE ASPIRIN

DO NOT take Aspirin if you:

- Are allergic (hypersensitive) to aspirin or any of the other ingredients. *For more information see Section 6, 'Further Information'.*
- Are allergic to any other pain relieving or anti-inflammatory medicines (eg NSAIDs or salicylates). *For more information see Section 4, 'Possible Side Effects'.*
- Have a disorder which causes excessive bleeding such as haemophilia.

- Have, or have had, a stomach or duodenal ulcer.
- Are on a high dose of methotrexate (15mg per week or more). If you are not sure, check with your doctor. Also see '*Using other medicines*'.
- Are pregnant or breast-feeding, unless advised by a doctor.
- Have severe heart, kidney or liver problems.
- Have asthma that is worsened by aspirin or any other NSAID.

Speak to your doctor before taking Aspirin if you:

- Suffer from tightness in the chest, asthma, nasal polyps, hayfever or allergies.
- Have low uric acid excretion, which is commonly associated with gout.
- Have a history of gastrointestinal disorders (regular stomach upsets).
- Have kidney or liver problems.
- Have problems with your circulation (kidney or heart disease)
- Have glucose-6-dehydrogenase deficiency (a hereditary condition that may result in anaemia).
- Are about to have surgery. Before the operation tell the doctor or surgeon that you are taking aspirin.
- Are elderly, as you are more likely to experience unwanted side effects.

If you are not sure whether any of the above apply to you, speak to your doctor or pharmacist before taking Aspirin.

Important information about some of the ingredients:

This medicine contains 150 mg sodium (main component of cooking/tablet salt) in each tablet. This is equivalent to 7.5% of the recommended maximum daily dietary intake of sodium for an adult.

Use in children:

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 under 16 years, unless on the advice of a doctor.

Using other medicines:

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

Aspirin can affect the way in which some medicines work. These medicines include:

- Medication to prevent blood clotting (eg warfarin, heparin, ticlopidine).
- Medication to treat heart problems or to lower blood pressure (eg ACE inhibitors or digoxin).
- Medication to treat gout (eg benzbromarone, probenecid).
- Diuretics (to treat water retention).
- Medication to treat epilepsy (eg sodium valproate, phenytoin).
- Medication to lower blood sugar if you are diabetic.

- Methotrexate (to treat psoriasis, rheumatoid arthritis, Crohn's disease and some types of cancer).
- Any pain-relieving or anti-inflammatory medicines (eg ibuprofen).
- Medication containing corticosteroids.
- Selective Serotonin Re-uptake Inhibitors (SSRIs) (to treat depression).

Taking with food and drink:

Avoid taking alcohol while taking Aspirin.

Pregnancy and breast-feeding:

Do not use Aspirin if you are pregnant, breastfeeding or trying for a baby unless directed by your doctor. Aspirin can prolong labour and affect blood clotting in the mother or baby.

Taking medicines containing aspirin may make it more difficult to become pregnant. This effect is reversible once you stop taking the medicine.

Always ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO TAKE ASPIRIN

Follow the directions below closely. You should ask your doctor or pharmacist if you are unsure how to use this medicine.

Aspirin tablets must always be dissolved in water before use.

Adults and children over 16:

Two tablets dissolved in half a glass (100ml) of water may be taken every 4 hours as required. Drink when effervescence subsides. You should not take more than 13 tablets in 24 hours.

Not recommended in children under 16.

The tablets should preferably be taken after eating.

Make sure you follow the dosage instructions and do not take more than the stated dose.

Do not take Aspirin for more than 3 days in a row. If symptoms persist, speak to your doctor or pharmacist.

If you take more Aspirin than you should:

If you think you have taken too many tablets you should go to your nearest Accident and Emergency Department or contact your doctor immediately. Take this leaflet with you and any packaging to show what you have taken.

4. POSSIBLE SIDE EFFECTS

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

The product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

If you experience any of the following side effects, **stop taking** Aspirin and go to your nearest Accident and Emergency Department or doctor immediately:

- An allergic reaction. Signs of allergic reaction may include: difficulty in breathing or swallowing, swelling of the face, lips, throat or tongue, skin rashes, large or itchy wheals on the skin, attacks of sneezing, runny nose and itching eyes or water retention.
- Bleeding from the stomach or bowel, which may result in black or tarry stools.
- Nausea, vomiting, indigestion, diarrhoea or stomach pain.
- Anaemia (reduction in the number of red blood cells).
- Heart failure with shortness of breath.
- Kidney impairment or failure.
- Dizziness or ringing in the ears.
- Increased bleeding/blood thinning (if you cut or injure yourself). This may include bleeding from the urinary tract, bleeding within the brain, or bleeding from the nose or gums.
- An asthma attack if you are asthmatic and sensitive to aspirin.
- Changes in normal liver activity in blood tests (very rare).

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ASPIRIN

Keep out of the reach and sight of children.

Do not store above 25 °C. Store in the original package to protect from moisture.

The tablets are packaged in individual foil pouches. If the pouch is opened and the tablet is not used immediately, dispose of the tablet. If the pouch is damaged or if the tablet is powdery or discoloured, do not use the tablet.

Do not use Aspirin after the expiry date which is stated on the carton and on the foil pouch. 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. FURTHER INFORMATION

What Aspirin contains:

Each effervescent tablet contains the **active substance** aspirin (acetylsalicylic acid) (300mg per tablet).

The **other ingredients** are citric acid anhydrous, docusate sodium, lemon flavour, malic acid, mannitol, povidone, saccharin sodium, sodium hydrogen carbonate, sodium carbonate anhydrous.

See section 2 'Important information about some of the ingredients' for sodium advice.

What Aspirin looks like and contents of the pack:

Aspirin comes in cartons containing 18 or 30 white effervescent tablets packaged in foil pouches. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18

Manufacturer:

Bayer Santé Familiale
33, Rue de l'Industrie
74240 Gaillard
France

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