



Alka-Seltzer®

Effervescent Tablets

Acetylsalicylic Acid (Aspirin) 324mg
Sodium Hydrogen Carbonate 1744mg
Citric Acid 965mg

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 Alka-Seltzer 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.

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1. WHAT IS ALKA-SELTZER® AND WHAT IS IT USED FOR?

Alka-Seltzer are effervescent tablets which dissolve in water to give a sparkling solution. The active substances are: aspirin (acetylsalicylic acid), sodium hydrogen carbonate and citric acid.

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.

Alka-Seltzer can be used for the:

- Treatment of mild to moderate pain including headache, migraine, backache (including lumbago), nerve pain (neuralgia and sciatica), period pain, toothache and sore throat.
- Symptomatic relief of colds and influenza.
- Relief of rheumatic pain (arthritis), muscle tenderness and stiffness (including fibrositis), muscular aches and pains, the pain of joint swelling and stiffness, strains and sprains.
- Effective reduction of high temperature.

2. BEFORE YOU TAKE ALKA-SELTZER®

DO NOT take Alka-Seltzer if you:

- Are allergic (hypersensitive) to aspirin, sodium hydrogen carbonate, citric acid or any of the other ingredients of Alka-Seltzer. *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 Alka-Seltzer 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-phosphate dehydrogenase (G6PD) 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 Alka-Seltzer.

Important information about some of the ingredients:

Each Alka-Seltzer tablet contains 477mg of sodium. This should be taken into consideration by people on a controlled sodium diet.

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 Alka-Seltzer.

Pregnancy and breast-feeding:

Do not use Alka-Seltzer if you are pregnant, breast-feeding 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 ALKA-SELTZER®

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

Alka-Seltzer 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. You should not take more than 8 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 Alka-Seltzer for more than 3 days in a row. If symptoms persist, speak to your doctor or pharmacist.

If you take more Alka-Seltzer 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 Alka-Seltzer 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** Alka-Seltzer 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).

If you have unusual stomach pains or react badly to this medicine in any other way, stop taking Alka-Seltzer and tell your doctor or pharmacist immediately.

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 HPRC 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 ALKA-SELTZER®

Keep out of the reach and sight of children.

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

This product is packaged in pouches containing 2 tablets. If the pouch is opened and a tablet is not used immediately, dispose of the tablet. If the pouch is damaged or if a tablet is powdery or discoloured, do not use the tablet.

Do not use Alka-Seltzer 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 Alka-Seltzer contains:

Each effervescent tablet contains the **active substances** aspirin (acetylsalicylic acid) (324mg per tablet), sodium hydrogen carbonate (1744mg per tablet) and citric acid (965mg per tablet).

The **other ingredients** are povidone, dimeticone, calcium silicate, docusate sodium, sodium benzoate (E211), sodium saccharin, natural and artificial lemon flavour and natural and artificial lime flavour.

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

What Alka-Seltzer looks like and contents of the pack:

Alka-Seltzer comes in cartons containing 10 or 20 white effervescent tablets packaged in foil pouches.

Marketing Authorisation Holder:

Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland

Manufacturer:

Bayer Bitterfeld GmbH
OT Greppin
Salegaster Chaussee 1
06803 Bitterfeld-Wolfen
Germany

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Bayer