

Package leaflet: Information for the user

Alka-Seltzer Effervescent Tablets

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

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 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.
- You must talk to your doctor if you do not feel better or if you feel worse after 3 days.

WHAT IS IN THIS LEAFLET:

1. What Alka-Seltzer is and what it is used for
2. What you need to know before you take Alka-Seltzer
3. How to take Alka-Seltzer
4. Possible side effects
5. How to store Alka-Seltzer
6. Contents of the pack and other information

1. What Alka-Seltzer is and what it is 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. What you need to know before you take Alka-Seltzer

DO NOT take Alka-Seltzer if you:

- Are allergic to aspirin, sodium hydrogen carbonate, citric acid or any of the other ingredients of this medicine (*listed in section 6*).
- Are allergic to any other pain relieving or anti-inflammatory medicines (e.g. 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 breastfeeding, unless advised by a doctor.
- Have severe heart, liver or kidney problems.
- Have asthma that is worsened by aspirin or any other NSAID.

Warnings and precautions

Talk to your doctor or pharmacist 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.

When taking Alka-Seltzer, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately when you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

Alka-Seltzer Effervescent Tablets contain sodium and sodium benzoate (E 211):

This medicine contains 477 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 23.85% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need one or more Alka-Seltzer Effervescent Tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

This medicine contains 0.013 mg sodium benzoate (E 211) in each effervescent tablet.

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.

Other medicines and Alka-Seltzer:

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 clotting (e.g. warfarin, heparin, ticlopidine).
- Medication to treat heart problems or to lower blood pressure (e.g. ACE inhibitors or digoxin).
- Medication to treat gout (e.g. benzbromarone, probenecid).
- Diuretics (to treat water retention).
- Medication to treat epilepsy (e.g. 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 (e.g. ibuprofen).
- Medication containing corticosteroids.
- Selective Serotonin Re-uptake inhibitors (SSRI's)(to treat depression).

Alka- Seltzer with food and drink:

Avoid taking alcohol while taking Alka-Seltzer.

Pregnancy, breast-feeding and fertility:

Do not use Alka-Seltzer if you are pregnant, breast-feeding or trying for a baby unless directed by your doctor.

Alka-Seltzer can cause kidney and heart problems in your unborn baby. It 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. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

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

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. 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, this medicine 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).

Frequency not known:

Acute myocardial ischemia (painful heart condition caused by lack of blood flow to the heart) with or without myocardial infarction (heart attack) occurring as part of an allergic reaction (Kounis syndrome).

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 HPRAs Pharmacovigilance; Website: www.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 this medicine out of the sight and reach 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 this medicine 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. Contents of the pack and other information

What Alka-Seltzer contains:

- The active substances are 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, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland

Manufacturer:

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