



Alka-Seltzer[®] XS

Aspirin, Paracetamol, Caffeine, Sodium Hydrogen Carbonate, Citric Acid

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 XS 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[®] XS AND WHAT IS IT USED FOR?

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

Aspirin belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). Aspirin and paracetamol are both used for the treatment of pain and reduction of fever. Aspirin also has anti-inflammatory properties. Caffeine acts as a mild stimulant, whilst citric acid and sodium hydrogen carbonate help relieve an upset stomach.

Alka-Seltzer XS can be used for the:

- Treatment of headache with an upset stomach, particularly when caused by too much to eat or drink.
- 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.
- Effective reduction of high temperature.

2. BEFORE YOU TAKE ALKA-SELTZER[®] XS

DO NOT take Alka-Seltzer XS if you:

- Are allergic (hypersensitive) to aspirin, paracetamol, caffeine, sodium hydrogen carbonate or citric acid.
- 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.

Speak to your doctor before taking Alka-Seltzer XS if you:

- Suffer from tightness in the chest or asthma.
- 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.
- Are about to have surgery. Before the operation tell the doctor or surgeon that you are taking aspirin.

If you are not sure whether any of the above apply to you, speak to a doctor or pharmacist before taking Alka-Seltzer XS.

Important information about some of the ingredients:

Each Alka-Seltzer XS tablet contains 472mg 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.
- 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.
- Medication containing corticosteroids.

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

- Metoclopramide (to treat nausea and vomiting).
- Domperidone (to treat nausea, vomiting, indigestion).
- Colestyramine (to treat high cholesterol).

Do not take other products containing paracetamol whilst taking this product.

Taking with food and drink:

Avoid taking alcohol while taking Alka-Seltzer XS.

Pregnancy and breast-feeding:

Do not take Alka-Seltzer XS 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.

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

3. HOW TO TAKE ALKA-SELTZER® XS

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

Alka-Seltzer XS 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.

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

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

If you take more Alka-Seltzer XS 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.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4. POSSIBLE SIDE EFFECTS

Like all medicines Alka-Seltzer XS can cause side effects although not everybody gets them.

If you experience any of the following side effects, **stop taking** Alka-Seltzer XS 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.
- Stomach bleeding, which may result in black or tarry stools.

- Nausea or vomiting.
- Dizziness or ringing in the ears.
- Diarrhoea.
- Increased bleeding/blood thinning (if you cut or injure yourself).
- 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 XS and tell your doctor or pharmacist immediately.

5. HOW TO STORE ALKA-SELTZER® XS

Keep out of the reach and sight of children.

Do not store above 25 °C. Store in a dry place. This product should be stored in its original carton.

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 XS 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 XS contains:

The **active substances** are aspirin (acetylsalicylic acid) (267mg per tablet), paracetamol (133mg per tablet), caffeine (40mg per tablet), sodium hydrogen carbonate (1723mg per tablet) and citric acid (954mg per tablet).

There are no other ingredients in Alka-Seltzer XS.

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

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

Alka-Seltzer XS comes in cartons containing 2, 10, 12, 20 or 30 white effervescent tablets packaged in foil pouches. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Bayer plc
Consumer Care Division
Bayer House, Strawberry Hill
Newbury, Berkshire RG14 1JA
United Kingdom

Manufacturer:

Bayer Bitterfeld GmbH
D-06803 Greppin
Germany

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Bayer