

ALKA-SELTZER® CLASSIC EFFERVESCENT TABLETS BAYER HEALTHCARE AG

Active ingredient: acetylsalicylic acid

Composition

Pharmaceutically active ingredients

1 effervescent tablet contains 324 mg acetylsalicylic acid,

Other ingredients

Citric acid, sodium bicarbonate, povidone 25, dime-thicone, calcium silicate, docusate sodium, sodium benzoate, saccharin sodium, flavouring, contains 477 mg sodium.

Dosage form and content

One pack of Alka-seltzer classic contains 10 (N1), 20 (N2) or 30 (N3) effervescent tablets.

Mode of action and therapeutic category

Analgesic and antipyretic agent from the group of anti-inflammatory substances

Manufacturer

Bayer Leverkusen

Indications

Milk to moderate pain, fever

Note

Due to the risk of reye's syndrome, children or adolescents with feverish illnesses should not take Alka-seltzer classic unless they have been instructed to do so by a doctor and other therapeutic measures have failed (see "what precautions should you take for children?") Alka-seltzer classic must not be taken for extended periods or at high doses without consulting a doctor or dentist.

Contraindications

When should you not use Alka-seltzer classic?

Alka-seltzer classic must not be used by patients with:

- Known hypersensitivity to the active ingredient acetylsalicylic acid or to salicylates, a group of substances related to acetylsalicylic acid.
- A pathologically increased tendency to bleed

Alka seltzer classic must not be used during the last trimester of pregnancy.

When should you consult a doctor before taking Alka-seltzer classic?

Described below are cases in which you should only take Alka-seltzer classic under certain circumstances and with particular caution. Please consult your doctor if any of these cases apply to you now or have applied to you in the past.

Alka-seltzer classic should be taken only with particular care (i.e with longer intervals between doses or at reduced doses) and under medical supervision if you:

- Are hypersensitive to other analgesic, anti-inflammatory or antirheumatic medicines or if you have other allergies (see also precautions)
- Are taking anticoagulant medicines (e.g coumarin derivatives) heparin (except low-dose heparin)).
- Suffer from bronchial asthma
- Have chronic or recurrent gastric or duodenal complaints, gastric or duodenal ulcers;
- Have pre-existing kidney damage.
- With severely impaired liver function.

Patients on a low sodium diet should not the sodium content of this medicine (see dosage and administration)

What precautions should you take during pregnancy?

A doctor must be informed if pregnancy occurs during a prolonged period of treatment with Alka-seltzer classic. Alka-seltzer classic should not be taken in the first and second trimesters of pregnancy without consulting a doctor.

A acetylsalicylic acid should not be taken in the last three months of pregnancy owing to an increased risk of complications for mother and child during delivery.

What precautions should you take if you are breast-feeding?

Small quantities of the active ingredient acetylsalicylic acid and its metabolites pass into the breast milk. Detrimental effects on the infant have not been reported to date; it is therefore generally not

necessary to interrupt breast-feeding for short term use at the recommended dosage for pain or fever. Nevertheless, if long-term use and/or higher doses (more than 8 tablets per day) have been prescribed in isolated cases, early weaning should be considered.

What precautions should be taken for children?

Alka-seltzer classic should not be taken by children or adolescents with feverish illnesses unless they have been instructed to do so by a doctor and other therapeutic measures have failed. Prolonged vomiting in conjunction with such illnesses could be a sign of reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.

Precautions and warnings

What precautions should be taken?

Patients who suffer from asthma hay fever, nasal polyps or chronic respiratory tract infections (particularly if they are accompanied by hay fever like symptoms) or who are hypersensitive to any type of analgesic or antirheumatic drugs are at risk of asthma attacks (analgesic intolerance / analgesic induced asthma) if they take Alka-seltzer classic. They should consult a doctor before using this product. The same applies to patients who react hypersensitively (allergically) to other substances in the form of skin reactions, pruritus or nettle rash. A doctor/dentist must be consulted or informed about any use of Alka-seltzer classic before operations.

The sodium benzoate content of this medicine may cause hypersensitivity reactions such as irritation to the skin and mucous membranes in predisposed patients. Use of this medicine is associated with an increased risk of jaundice in new-born babies.

What precautions should be taken when driving, operating machinery or working without a secure foothold?

No special precautions are necessary.

What other precautions must be taken?

Long-term use of high doses of analgesic medicines taken contrary to instructions can cause headaches which must not be treated by even higher doses of the medicine.

In general habitual consumption of analgesic medicines particularly combinations of several analgesic active substances, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy)

Interactions with other drugs

What other medicines affect the way Alka-seltzer classic works, and what must you bear in mind if you are taking other medicines at the same time?

Please note that this information may also apply to medicines used recently

Alka-seltzer classic increases:

- The effect of anticoagulant drugs (e.g coumarin derivatives and heparin)
- The risk of gastrointestinal bleeding if taken concomitantly with alcohol or medicines that contain cortisone or cortisone like substances;
- The effect of certain blood glucose lowering medicines (sulphonylureas)
- The effects and unwanted effects of methotrexate;
- Blood levels of digoxin barbiturates and lithium
- The desirable and unwanted effects of a particular group of analgesic and antirheumatic medicines (non steroidal anti-inflammatories)
- The effect of certain antibiotics (sulphonamides and sulphonamide combinations (e.g sulphamethoxazole/trimethoprim)
- The effect of triiodothyronine, a medicine for treating hypothyroidism.
- The effect of valproic acid, a medicine for treating cerebral convulsions.

Alka-seltzer classic weakens the action of:

- Certain medicines that increase the excretion of urine (aldosterone antagonists and loop diuretics)
- Blood pressure lowering medicines
- Gout remedies that promote the excretion of uric acid (e.g probenecid sulphapyrazone)

Accordingly patients should not take Alka-seltzer classic in conjunction with any of the above mentioned substances unless expressly instructed to do so by a doctor.

What foods and drinks should you avoid?

Consumption of alcohol should be avoided as far as possible during therapy with Alka-seltzer classic.

Dosage and administration

Unless otherwise prescribed by your doctor you should take Alka-seltzer classic as shown below. Please follow the directions carefully as otherwise Alka-seltzer classic cannot work properly.

How much Alka-seltzer classic should you take and how often?

Unless otherwise prescribed, adults should take:

Single dose: 2 effervescent tablets

Daily dose: up to 8 effervescent tablets

The single dose can be taken at intervals of 4-8 hours if necessary, up to a maximum of 4 doses a day.

Note

For patients with impaired liver or kidney function, the dosage must be reduced or the dosage intervals extended.

For patients on a low-sodium diet: 1 effervescent tablet contains 477 mg sodium.

How and when should you take Alka-seltzer classic?

Dissolve the effervescent tablets in plenty of liquid. Do not take Alka-seltzer classic on an empty stomach.

For how long should you take Alka-seltzer classic?

For pain or fever, Alka-seltzer classic should not be taken longer than 3-4 days without consulting your doctor or dentist.

Overdosage and incorrect use**What should you do if you take too much Alka-seltzer classic (either intentionally or by accident)?**

Dizziness and ringing in the ears, particularly in children and elderly patients, may indicate serious poisoning. Please notify your doctor if you suspect an over dosage of Alka-seltzer classic. He will decide on the necessary measures to be taken depending on the severity.

Side effects**What side effects can occur when using Alka-seltzer classic?**

Hypersensitivity reactions (attacks of difficult breathing, skin reactions) may occur in rare cases, especially in asthmatics.

Gastrointestinal complaints such as stomach pains and slight gastrointestinal blood loss (microhaemorrhage), nausea vomiting and diarrhea are very rare.

Isolated cases of impaired hepatic and renal function a reduction in blood glucose levels (hypoglycaemia) and particularly severe skin rashes (including erythema exsudativum multiforme) have been reported. Low-dose acetylsalicylic acid reduces the excretion of uric acid, and this may trigger an attack of gout in susceptible patients. Central nervous system disorders may occur during long term or chronic use; these include headaches, dizziness vomiting, ringing in the ears, impaired vision or drowsiness, and also anaemia due to a shortage of iron (iron-deficiency anaemia)

If you experience side effects that are not mentioned in this information leaflet, please inform your doctor or pharmacist.

What action should be taken if any of these side effects occur?

If you experience any of the above-mentioned side effects, do not take any more Alka-Seltzer classic. Notify your doctor so that he can determine the severity of the side effects and decide on any necessary further action.

You should stop taking Alka-Seltzer classic at the first signs of hypersensitivity.

Information on the shelf-life of the product.

The expiry date of this pack is printed on the box and on the tablet strips. Do not use the product after this date.

Do not store at temperature above 25°C

Date of preparation:

June 2000 (D7)

Keep medicines out of the reach of children.