



ALEVE®

All Day Pain Relieve: 1 Tablet Every 8–12 hours

What is ALEVE® and when should it be used?

One film-coated tablet contains 220mg naproxen sodium, equivalent to 200mg of naproxen as active ingredient and 20mg of sodium (low content, similar to a slice of wheat bread).

It also contains povidone, microcrystalline cellulose, talc, magnesium stearate, purified water and Opadry (blue) as excipients. ALEVE® is lactose and gluten free.

ALEVE® film-coated tablets are supplied in carton of 12's.

ALEVE® provides fast-acting, long-lasting relief for the temporary management of the pain and discomfort associated with:

- Headaches
- Backaches
- Muscular aches & pains
- Minor pain of arthritis
- Toothaches
- Menstrual pain

ALEVE® also:

- relieves inflammation and stiffness
- reduces fever, such as that associated with common cold.

How should ALEVE® be used?



Each dose should be taken orally with a glass of water, with or without meals. Consider taking each dose with meals if you have a sensitive stomach. If taken with food, the product may take longer to work.



ALEVE® should not be taken for more than 10 consecutive days.



ADULTS:

- 1 tablet every 8 to 12 hours while symptoms persist.
- For the first dose, 2 tablets may be taken together in the first hour if required.



- Do not exceed 3 tablets in 24 hours unless directed to do so by a doctor.



CHILDREN:

- Do not give this drug to children under 12 years.



ELDERLY (65 years old and over):

- Maximum of 2 tablets per day, unless directed to do so by a doctor.

RESTRICTED

ALEVE® should not be used by patients:

- who have previously exhibited allergy to naproxen sodium
- in whom acetylsalicylic acid (Aspirin®) or other anti-inflammatory and pain relieving drugs have induced allergic reactions
- with a stomach or intestinal ulcer or other stomach disorders, or who have impaired kidney function and heart failure

What are the precautionary measures to be observed when taking ALEVE®?

- A doctor should be consulted if the pain or fever persists or gets worse or if any unusual symptoms arise.



- ALEVE® should not be taken, except under close supervision of a doctor, by patients with a history of disease of the stomach or of the intestines (e.g. ulcer). Stomach and intestinal pain should not be treated with ALEVE®.



- ALEVE® should be taken under medical supervision if you have blood coagulation disorders or are receiving drug therapy that interferes with blood coagulation.
- ALEVE® should not be taken with other anti-inflammatory drugs (including other naproxen and naproxen sodium presentations) and pain relieving drugs except under a doctor's direction.



- ALEVE® can cause allergic reactions in asthmatics or patients allergic to Aspirin® and to other anti-inflammatory or pain relieving drugs.



A doctor or pharmacist should be consulted:

- If any other medicines are taken on a regular basis;
- If heartburn, upset stomach or stomach pain occurs;
- If you are prone to allergies
- If patients are taking diuretics, lithium, methotrexate or medication for high blood pressure and low dose aspirin for cardiovascular protection.
- If you previously have had a heart attack or stroke.

Do not exceed the indicated dosage.

The lowest effective dose should be taken for the shortest possible time to reduce the risk of side effects.

Naproxen sodium may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose and duration.

Stop taking the product and contact your doctor immediately if you develop signs and symptoms of heart problems or stroke, such as chest pain, shortness of breath, weakness in one part or side of body, or blurring of speech.



Can ALEVE® be taken during pregnancy or breast-feeding?

Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby.

ALEVE® should not be taken by pregnant women except under medical supervision.

Do not use during the last 3 months of pregnancy.

The medication should be avoided in patients who are breast-feeding.

Effects on fertility

There is some evidence that drugs which inhibit cyclo-oxygenase / prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation.

The effect on ovulation is reversible upon the withdrawal of the treatment.

What are the adverse reactions that ALEVE® may have?

ALEVE® tablets like most medications can cause unwanted side effects in some patients.

The most common side effects are:

- abdominal discomfort
- swelling
- stomach discomfort and indigestion
- ringing in the ears
- dizziness
- nausea and headache
- constipation
- drowsiness
- laboured breathing

Serious skin reactions such as exfoliative dermatitis, Steven's-Johnson syndrome and toxic epidermal necrolysis have been reported very rarely in association with the use of NSAIDs. ALEVE® should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

In the case of unusual reactions, stop treatment immediately and consult your doctor.

What should you do in case of an overdose?

Significant overdosage can be characterized by dizziness, drowsiness, upper abdominal pain, abdominal discomfort, heartburn, indigestion, nausea and vomiting, transient changes in liver function, decreased level of prothrombin clotting factor in the blood (hypoprothrombinemia), kidney dysfunction, increased acid levels in the blood (metabolic acidosis), apnea, or disorientation.

However, in the event of an overdose or accidental ingestion, seek medical help immediately. The stomach may be emptied and usual supportive measures like administration of activated charcoal may be employed.

What should be taken into account in addition to this?

ALEVE® should be kept out of reach of children.

For the shelf-life, please refer to labels.

Keep your ALEVE® tablets in a dry place, away from light and at a temperature below 30°C.

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RESTRICTED