

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALEVE 24 Hour.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist or doctor will be able to advise you about the risks and benefits of taking ALEVE 24 Hour.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What ALEVE 24 Hour is used for

ALEVE 24 Hour belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

ALEVE 24 Hour relieves persistent pain and reduces inflammation (swelling, redness and soreness) that may occur in the following:

- body pain
- back pain
- neck and shoulder pain
- muscle pain
- sprains and strains
- osteoarthritis
- arthritic and rheumatic conditions
- period pain
- dental pain
- sinus pain
- cold and flu

ALEVE 24 Hour can also provide temporary relief of stiffness associated with arthritis.

Aleve 24 Hour should be used if pain is likely to last for longer than 12 hours.

Although ALEVE 24 Hour can relieve the symptoms of pain and inflammation, it will not cure your condition.

Use in children statement:

ALEVE 24 Hour is not recommended for use in children (under the age of 12), as there have been no studies of its effects in children.

ALEVE 24 Hour is not addictive.

It is available from your pharmacist.

Before you take ALEVE 24 Hour

When you must not take it

Do not take ALEVE 24 Hour if you have an allergy to:

- any medicine containing naproxen (the active ingredient in ALEVE 24 Hour), aspirin or any other NSAIDs
- any of the ingredients listed at the end of this leaflet

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Some of the symptoms of an allergic reaction may include:

- asthma, wheezing, difficulty breathing or shortness of breath

- swelling of the face, lips, tongue or other parts of the body which may cause difficulty in swallowing or breathing
- hives, itching or rash
- fainting

If you are allergic to aspirin or NSAID medicines and take ALEVE 24 Hour, these symptoms may be severe.

Do not take ALEVE 24 Hour if at the present time you have an ulcer (gastric or duodenal) or other stomach disorders, or bleeding from the stomach or bowel.

If you take it, your stomach problem may become worse.

Do not take ALEVE 24 Hour if you have impaired kidney function or heart failure.

Do not take ALEVE 24 Hour in the last 3 months of pregnancy. It may affect the baby, and also delay labour and birth.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take this medicine if you are aged 65 years old or over unless your doctor has told you to.

Your doctor might tell you to take other lower-dose naproxen tablets instead of Aleve 24 Hour so that you may use the lowest effective dose.

Do not give this medicine to a child under 12 years of age.

ALEVE 24 Hour is not recommended for use in children under 12 years of age, as there is not enough information on its use in children under that age.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have any of these health problems/medical conditions at the present time:

- heart disease
- kidney disease
- liver disease
- high blood pressure
- a tendency to bleed or other blood problems/ such as anaemia
- asthma

Your pharmacist or doctor may want to take special precautions if you have any of these conditions.

Tell your pharmacist or doctor if you have or ever have of the following medical conditions:

- ulcers (gastric or duodenal)
- severe attacks of indigestion or other stomach trouble
- diseases of the bowel (e.g. Crohn's disease, ulcerative colitis)
- bleeding from your rectum (back passage)

Tell your pharmacist or doctor if you have an infection at the present time.

If you take ALEVE 24 Hour while you have an infection, some of the signs of the infection may be hidden (pain, fever, swelling, redness). You may think, mistakenly, that you are better or that your infection is not serious.

Tell your pharmacist or doctor if you are pregnant, or plan to become pregnant or are breast-feeding.

Like most NSAID medicines, ALEVE 24 Hour is not recommended to be used during pregnancy or when breast-feeding. Your pharmacist or doctor will discuss with you the benefits and risks of taking it.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking ALEVE 24 Hour.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and naproxen may interfere with each other. These include:

- aspirin, salicylates and other NSAIDs or anti-inflammatory medicines or other medicines for pain relief
- phenytoin, a medicine used to treat epilepsy
- serotonin reuptake inhibitors, medicines that are often used for the treatment of depression
- glucocorticoids, a class of steroid hormones
- probenecid, a medicine used to treat gout
- medicines used to treat high blood pressure, like beta blockers, ACE-Inhibitors and angiotensin receptor blockers
- anticoagulant/antiplatelet medicines e.g. warfarin, coumarins, aspirin
- lithium, a medicine used to treat some types of depression
- diuretics, also called fluid or water tablets
- methotrexate, a medicine used to treat arthritis and some types of cancer
- digoxin, a medicine used to treat heart failure
- cyclosporin, a medicine used to suppress the immune system
- zidovudine, a medicine used to treat HIV infection

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take ALEVE 24 Hour

Follow all directions given to you by your pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist for help.

How much to take/use

Adults and children from 12 years: Take one tablet every 24 hours as required. Do not take more than one tablet a day.

How to take it

Swallow one tablet whole with a full glass of water or milk. Do not break, crush or chew the tablets.

When to take it

Tablet should be taken with or without food. If you have a sensitive stomach, take with food. If taken with food, the product may take longer to work.

How long to take it

Do not use ALEVE 24 Hour for more than a few days at a time unless your doctor has told you to.

Do not exceed the recommended dose. Excessive use can be harmful.

If symptoms persist or worsen, see your doctor to ensure that they are not due to serious illness. The use of Aleve 24 Hour could mask potentially serious infections.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much ALEVE 24 Hour. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

If you take/use too much ALEVE 24 Hour, you may feel nausea (feeling sick), vomiting, heartburn, indigestion or cramps.

While you are taking ALEVE 24 Hour

Things you must do

If you become pregnant while taking Aleve 24 Hour, tell your pharmacist or doctor immediately.

He/she can discuss with you the risks of taking it while you are pregnant.

If you are about to start using any new medicine, remind your pharmacist or doctor that you are taking Aleve 24 Hour. Take this medicine exactly as directed by your pharmacist or doctor.

If you do not follow these instructions, your condition may not improve or you may have unwanted side effects.

If you are going to have surgery, make sure the surgeon and anaesthetist know that you are taking Aleve 24 Hour.

NSAID medicines can slow down blood clotting.

If you get an infection while taking Aleve 24 Hour, tell your doctor.

This medicine may hide some of the signs of an infection (pain, fever, swelling, redness). You may think, mistakenly, that you are better or the infection is not serious.

Talk to your pharmacist or doctor if you feel that the medicine is not helping.

This will help him/her determine the best treatment for you.

Tell any other doctor, dentist or pharmacist who treats you that you are taking ALEVE 24 Hour.

Things you must not do

Do not take any medicines used to treat arthritis while you are taking Aleve 24 Hour without first telling your doctor or pharmacist.

This includes:

- aspirin or other salicylates
- any NSAID or anti-inflammatory medicine

Do not take ALEVE 24 Hour to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give ALEVE 24 Hour to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose unless your doctor tells you to.

Things to be careful of

Aleve 24 Hour is not recommended if you are aged 65 years old or over unless your doctor has told you to take this medicine.

Taking this medicine may increase the risk of you getting unwanted effects, such as stomach or heart problems.

Be careful driving or operating machinery until you know how ALEVE 24 Hour affects you.

This medicine may cause dizziness, drowsiness or blurred vision in some people. If this happens, do not drive, use or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALEVE 24 Hour.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you get an allergic reaction stop taking and see your doctor immediately.

If you are aged 65 years old or over you may have an increased chance of getting side effects. Report any side effects promptly to your pharmacist or doctor.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps or stomach pain
- loss of appetite
- diarrhoea, pain in the stomach, wind
- dizziness, light-headedness
- drowsiness, sleepiness, disorientation
- headache
- change in mood, e.g. feeling depressed, anxious, irritable or nervous
- buzzing or ringing in the ears
- sore or dry mouth or tongue
- trembling, sleeplessness, nightmares
- sore mouth or tongue
- altered taste sensation
- feeling thirsty
- aching muscles, muscle tenderness or weakness, not caused by exercise

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish-purplish or blue-black blotches under the skin
- signs of anaemia such as tiredness, being short of breath, looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of the urine passed, burning feeling when passing urine
- signs of a liver problem such as tiredness, lack of energy, itching of the skin, yellowing of the skin and eyes, pain in the abdomen
- unusual weight gain, swelling of ankles or legs
- get sunburnt more quickly than normal
- eye problems such as blurred or double vision, sore red eyes, itching
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- fast or irregular heartbeats, also called palpitations
- difficulty hearing, deafness
- severe skin rashes

These are serious side effects. You may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- vomiting blood or what look like coffee grounds
- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing or shortness of breath
- sudden or severe rash, itching or hives on the skin
- fainting or seizures (fits)
- pain or tightness in the chest

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your pharmacist or doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking ALEVE 24 Hour

Storage

Keep your tablets in the strip pack until it is time to take them.

If you take the tablets out of the strip pack they will not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store ALEVE 24 Hour or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ALEVE 24 Hour or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ALEVE 24 Hour tablets are blue, capsule-shaped, film-coated tablet debossed with “BAYER” on one side and “660” on the other. It comes in strip packs of 4, 8, 12 and 16 tablets.

Ingredients

Active ingredient:

Each ALEVE 24 Hour is a bilayer tablet with an immediate release layer containing 264 mg naproxen sodium and an extended release layer containing 396 mg of naproxen sodium.

Inactive ingredients:

- povidone
- microcrystalline cellulose
- purified talc
- magnesium stearate
- purified water
- hypromellose
- lactose
- silica colloidal anhydrous
- titanium dioxide
- macrogol 8000
- indigo carmine aluminium lake
- carnauba wax

ALEVE 24 Hour also contains galactose

ALEVE 24 Hour does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier/Distributor

Bayer Australia Ltd
875 Pacific Highway
Pymble NSW 2073

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