

NAXEN®

Naproxen

250 mg tablet

What is in this leaflet

Please read this leaflet carefully before you start using NAXEN.

This leaflet answers some common questions about NAXEN. 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 doctor has weighed the risks of you using NAXEN against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NAXEN is used for

NAXEN tablets contain a medicine called naproxen. Naproxen belongs to a group of medicines called 'Non-Steroidal Anti-Inflammatory Drug' (or NSAIDs). Naproxen reduces pain and inflammation (swelling, redness and heat) but it will not cure your condition.

NAXEN is used in adults to relief symptoms associated with:

- Different types of arthritis including rheumatoid arthritis, osteoarthritis
- A disease of the joints in the spine (ankylosing spondylitis)
- Tendonitis and bursitis
- Acute gout (a disease with painful swollen joints)
- Period pain

NAXEN is used in children over 5 years of age to relief symptoms associated with:

- Juvenile Rheumatoid Arthritis

Your doctor may have prescribed NAXEN for another reason.

Ask your doctor if you have any questions about why NAXEN has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take NAXEN

When you must not take it

Do not take NAXEN if:

- You are allergic to naproxen, naproxen sodium or any of the other ingredients of this medicine (listed in Product description at the end of this leaflet).
- You are allergic to aspirin, other NSAIDs (such as ibuprofen or diclofenac) including other naproxen containing medicines.

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.

Symptoms of an allergic reaction to NSAIDs may include: Asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash, fainting.

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

Do not take NAXEN if:

- aspirin or other NSAIDs have given you asthma, or rhinitis (hayfever symptoms such as watery eyes, sneezing, runny nose, stuffiness, itchy nose, throat and eyes) in the past
- you are vomiting blood or coffee-ground-like material
- you are bleeding from the rectum (back passage), have bloody diarrhoea or black sticky bowel motions (stools)
- you have a peptic ulcer (i.e. duodenal or stomach ulcer), or have had peptic ulcers before
- you have a tendency to bleed when incurring minor accidents or to spontaneously bleed (haemorrhagic diathesis)
- you have liver disease
- you are about to have or have recently had or heart bypass surgery
- you are taking other medications which contain naproxen or naproxen sodium
- you have severe heart failure

NAXEN is not recommended for use in children under the age of 5 years, as the safety and effectiveness has not been established in this age group.

Do not take NAXEN after the expiry date (EXP) printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not take NAXEN if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using NAXEN talk to your doctor.

Before you start to take it

Tell your doctor if:

- you have any allergies to any other medicines including aspirin or other NSAID medicines

- you are allergic to any other medicines, foods, preservatives or dyes. Your doctor will want to know if you are prone to allergies.

Tell your doctor if:

- You are **pregnant or intend to become pregnant**, NAXEN may impair fertility and is therefore not recommended in women attempting to conceive. NAXEN may also affect your developing baby if you take it during pregnancy. If it is necessary for you to take NAXEN, your doctor will discuss the risks versus benefits of taking it during pregnancy.
- You are **breast-feeding** or intend to breast-feed, NAXEN passes into breast milk. Therefore, NAXEN should not be taken whilst breast-feeding mothers unless the benefit outweighs the potential risk.
- You have or have had any medical conditions, especially the following:
 - indigestion, heartburn, stomach ulcers or other stomach problems
 - bleeding from the back passage or vomiting blood
 - intestinal or bowel problems such as ulcerative colitis
 - liver or kidney disease
 - heart failure
 - stroke
 - heart problems such as previous heart attack or high blood pressure
 - swelling of the feet or ankles
 - a tendency to bleed or other blood problems, such as anaemia
 - nasal polyps, rhinitis
 - you have a history of alcoholism
 - you smoke
 - you are on a low sodium diet
 - you have low salt levels in your blood
 - swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing

- **You have an infection at the present time.** If you take NAXEN while you have an infection, some of the signs of the infection may be hidden for example redness, pain, swelling or fever. You may think, mistakenly, that you are better or that the infection is not serious.
- **you plan to have surgery** as NAXEN can prolong bleeding.
- **you are elderly** as older people may require a lower dose for the shortest possible duration

If you have not told your doctor about any of the above, tell them before you start using NAXEN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking NAXEN.

Some medicines may interfere with NAXEN. These include:

- Antacids or medicines used to treat heartburn and indigestion
- Other NSAID medicines, aspirin or salicylates
- Cholestyramine (a medicine used to treat high cholesterol levels)
- Diuretics (also called water/fluid tablets)
- Lithium (a medicine used to treat some types of depression)
- Probenecid (a medicine used to treat gout)
- Phenytoin (a medicine used to treat epilepsy)
- Methotrexate (a medicine used to treat arthritis and some cancers)
- Sucralfate (a medicine used to treat and prevent stomach ulcers)
- Warfarin (a medicine used to prevent blood clots)

- Heparin (a medicine used to prevent blood clots)
- Group of medicines used to treat high blood pressure including ACE inhibitors, angiotensin receptor antagonists and beta-blockers
- Sulfonylureas (group of medicines used to treat diabetes)
- Selective serotonin reuptake known as SSRIs (medicines used to treat some types of depression)
- Steroids (medicines used to treat inflammation)
- Zidovudine (a medicine used to treat HIV infection)
- Sodium bicarbonate (a medicine used to treat stomach upset or ulcers)

These medicines may be affected by NAXEN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NAXEN.

Ask your doctor or pharmacist if you are not sure about this list of medicines

How to take NAXEN

How much to take

Take NAXEN exactly as your doctor has prescribed. Your doctor will tell you how many NAXEN tablets to take each day.

If you are an older patient, have kidney or liver problems, your doctor may give you a lower dose.

Adults:

The usual dose is 500 mg to 1000 mg a day depending upon your condition.

Children over 5 years

The usual dose is 10 mg/kg/day given as two divided doses at 12-hour intervals.

When to take it

NAXEN tablets should be swallowed whole with liquid. It is recommended to take NAXEN with or after food as this may help reduce the possibility of an upset stomach.

How long to take it

Do not take NAXEN for longer than your doctor says.

Depending on your condition, you may need to use NAXEN, only once, for a few days, a few weeks or for longer periods.

Taking NAXEN for **arthritis** will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis, NAXEN should be taken every day for as long as your doctor prescribes.

Taking NAXEN for **tendonitis** and **bursitis** is usually only needed for a few days.

Taking NAXEN for **period pain** is usually only needed as soon as period pains begin at the beginning of each menstrual cycle.

For **gout**, NAXEN tablets are usually taken until the attack has passed.

Ask your doctor if you are not sure how long to take NAXEN for.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember and then continue taking it as you would normally.

Do not double a dose to make up for one you have missed. If you have trouble remembering your dose or you are not sure what to do, ask your pharmacist for some hints.

While you are taking NAXEN

Things you must do

If you become **pregnant** while taking NAXEN, tell your doctor immediately.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NAXEN.

Ask your doctor and pharmacist before you start taking any **new medicines**.

Tell your doctor you are taking NAXEN, if you are going to have **surgery**,

Tell your doctor that you are taking NAXEN if you are going to have any **laboratory tests**, as this medicine can affect the results of some of these tests.

Tell your doctor if you get an **infection** while using NAXEN. As this medicine may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition

Things you must not do

Do not stop taking NAXEN tablets or change the dose without first checking with your doctor.

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

Do not use NAXEN to treat other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how NAXEN affects you. As with other

NSAID medicines, NAXEN may cause dizziness or light-headedness in some people. Make sure you know how you react to NAXEN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If you drink alcohol, dizziness or light-headedness may be worse.

In case of overdose

If you take too much (overdose)

If you take too much NAXEN, you may experience drowsiness, pain or tenderness in the stomach, stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much NAXEN. Do this even if there are no signs of discomfort or poisoning.

Side effects

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

NAXEN helps most people with pain due to inflammation, but it may have unwanted side effects in a few people. 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. The elderly are more likely to get side effects from medicines.

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), indigestion, heartburn

- pain in the stomach, constipation, diarrhoea
- loss of appetite, dizziness, light-headedness
- headache, drowsiness
- buzzing or ringing in the ears
- dry mouth
- aching muscles, muscle tenderness or weakness, not caused by exercise

These side effects of NAXEN are usually mild.

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

- bleeding or bruising more easily than normal, reddish-purplish or blue-black blotches under the skin
- eye problems such as blurred vision
- persistent or severe headache
- palpitations (fast or irregular heartbeats)
- deafness, difficulty hearing
- unusual weight gain, swelling of ankles or legs
- yellowing of the skin or eyes

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- vomiting coffee-ground-like material or blood
- bloody diarrhoea, bleeding from the rectum (back passage), or have black sticky bowel motions (stools)
- severe tenderness or pain in any part of the stomach
- wheezing, difficulty breathing or shortness of breath
- swelling of the face, tongue or lips which may cause difficulty in swallowing or breathing
- sudden or severe itching, skin rash and hives
- fainting, seizures or fits
- tightness or pain in the chest
- severe dizziness, spinning sensation

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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking NAXEN

Storage

Keep the tablets in a cool dry place where the temperature stays at or below 30°C. Do not keep your tablets in the refrigerator.

Heat and dampness can destroy some medicines. Therefore, do not store NAXEN in a bathroom or near a sink or leave it in the car or on window sills.

Keep NAXEN 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

Return any unused or expired NAXEN tablets to your local pharmacy for disposal.

Product description

What it looks like

NAXEN tablets are yellow, biconvex, round tablet of 11 mm diameter with one face engraved NX250 and having a bisecting score. They come in bottles of 100 and 500 tablets. However, not all pack sizes may be marketed.

Ingredients

Active ingredient(s):

Naproxen

Inactive ingredients:

Lactose monohydrate, magnesium stearate, maize starch, povidone, quinoline yellow, sodium starch glycolate, sunset yellow FCF

Sponsor details

NAXEN is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

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New Zealand

Phone: (09) 835 0660

Date of preparation

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