

NOFLAM

Naproxen Tablets 250 mg and 500 mg



What is in this leaflet

This leaflet answers some common questions about NOFLAM tablets. 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 taking this medicine against the benefits they expect it will have for you.

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 NOFLAM is used for

NOFLAM contains the active ingredient naproxen.

NOFLAM relieves pain and reduces inflammation (swelling, redness and heat) associated with:

- different types of arthritis including rheumatoid arthritis, osteoarthritis
- arthritis in children (juvenile arthritis)
- ankylosing spondylitis (a disease of the joints in the spine)
- muscle and bone ailments such as sprains, strains, lower back pain (lumbago), rheumatism and tendonitis (e.g. tennis elbow)
- gout (a disease with painful swollen joints)
- pain following surgery
- period pain.

NOFLAM belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or

NSAIDs). There are many different types of NSAIDs used to treat pain and inflammation. Although NOFLAM can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor, however, may have prescribed NOFLAM for another purpose.

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

There is no evidence that NOFLAM is addictive.

NOFLAM is available only with a doctor's prescription.

Before you take NOFLAM

When you must not take it

Do not take NOFLAM if you have an allergy to:

- any medicine containing naproxen such as Synflex[®], Naprosyn[®], Naxen[®], Sonaflam[®] or Naprogesic[®].
- any of the other ingredients also contained in the tablet (these are listed at the end of this leaflet)
- aspirin or any other NSAID medicine. Examples of NSAIDs include ibuprofen, Nurofen[®], diclofenac, Voltaren[®].

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

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the

face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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

Do not take NOFLAM if:

- aspirin or other NSAIDs have given you asthma, nasal polyps or rhinitis (hay fever symptoms such as runny nose, stuffiness, watery eyes, sneezing, itchy nose, throat and eyes) in the past
- you are vomiting blood or material that looks like coffee grounds
- you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- you have a peptic ulcer (i.e. stomach or duodenal ulcer)
- you have a tendency to spontaneously bleed or bleed when incurring minor accidents (haemorrhagic diathesis)
- you have severe liver problems
- you have asthma
- you have severe heart failure
- you are undergoing treatment of pain related to coronary artery bypass grafting (CABG) - surgery on the blood vessels supplying the heart.

Do not give NOFLAM to children under 2 years of age.

The safety and effectiveness in children under 2 have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is

damaged or shows signs of tampering.

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

If you are not sure if you should be taking NOFLAM, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

NOFLAM may impair fertility and is not recommended in women attempting to conceive. NOFLAM may affect your developing baby. If it is necessary for you to take NOFLAM, your doctor will discuss the risks and benefits of taking it during pregnancy.

Do not take NOFLAM if you are in labour or during the last few days before the expected birth as it may harm you and/or affect the baby.

Tell your doctor if you are breast-feeding or plan to breast-feed.

NOFLAM passes into breast milk. Therefore there is a possibility that the breastfed baby may be affected. Your doctor will discuss the risks and benefits of taking NOFLAM if you are breast-feeding.

Tell your doctor if you have or have had any other health problems, especially the following:

- rhinitis (sneezing, runny or blocked nose), nasal polyps
- heartburn, indigestion, stomach ulcers or other stomach problems
- inflammatory bowel disease such as ulcerative colitis or Crohn's disease
- kidney or liver problems
- heart problems, such as cardiovascular disease, atherosclerotic (narrowing of the blood vessels) cardiovascular disease, previous heart attack, CABG

surgery, high blood pressure, heart failure or angina/chest pain

- stroke
- fluid retention or swelling of the hands, ankles or feet
- you are or have been dependent on alcohol
- a tendency to bleed easily
- you are on a low sodium diet
- you have low salt levels in your blood
- suffer from hypovolaemia – a blood disorder consisting of a decrease in the volume of circulating blood
- you have a history of allergies resulting in swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- are or have been a smoker.

Tell your doctor if you currently have an infection.

If you take NOFLAM while you have an infection, the tablets may hide some of the signs of an infection (e.g. pain, fever). This may make you think mistakenly, that you are better or that your infection is not serious.

Tell your doctor if you plan to have surgery.

NOFLAM can prolong bleeding.

If you have not told your doctor about any of the above, tell him or her before you start taking NOFLAM.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

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

- aspirin, salicylates or other NSAID medicines
- antacids, medicines used to treat indigestion and heartburn
- sucralfate, a medicine used to treat and prevent stomach ulcers
- sodium bicarbonate, a medicine used to treat stomach upset or ulcers

- cholestyramine, a medicine used to treat high cholesterol levels
- lithium, a medicine used to treat some types of depression
- probenecid, a medicine used to treat gout
- furosemide, a diuretic, also called fluid or water tablets
- phenytoin, a medicine used to treat epilepsy
- methotrexate, a medicine used to treat arthritis, and some cancers
- medicines used to stop blood clots, such as warfarin, heparin and dicoumarol derivatives
- steroids, medicines used to treat inflammation
- medicines used to treat high blood pressure including ACE inhibitors, angiotensin receptor antagonists and beta blockers
- certain antibiotics called sulfonamides
- some medicines used to treat diabetes called sulfonylureas
- serotonin reuptake inhibitors, also known as SSRIs, medicines used to treat some types of depression
- zidovudine, a medicine used to treat HIV infections.

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

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

Ask your doctor or pharmacist if you are not sure about this list of medicines or have any questions.

How to take NOFLAM

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Take NOFLAM exactly as your doctor has prescribed.

Your doctor will tell you how many NOFLAM tablets you should take each day.

Adults

The usual starting dose is 500 mg to 1000 mg a day depending upon your condition, and thereafter 500 mg a day in divided doses.

Children

The usual dose for children over 5 years is 10mg/kg/day given as two divided doses at 12 hour intervals. **NOFLAM is not recommended for children under 5 years of age.**

Elderly patients and those with liver or kidney problems may require smaller doses. Older people may be at more risk of developing stomach ulcers and therefore may be prescribed a lower dose.

How to take it

Swallow NOFLAM tablets whole with a glass of water.

It is recommended to take NOFLAM with or after food as this may help reduce the possibility of an upset stomach.

When to take it

Take NOFLAM at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking NOFLAM for as long as your doctor tells you.

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

As with other NSAID medicines, if you are using NOFLAM for arthritis, it will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis, NOFLAM should be taken every day for as long as your doctor prescribes.

For pain, sprains and strains, NOFLAM is usually needed for shorter periods.

For period pain (menstrual cramps), NOFLAM is usually taken during each menstrual cycle as soon as period pains begin and continued for up to 5 days, if necessary.

For gout, NOFLAM is usually taken until the attack has passed.

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 the one you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much NOFLAM. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

The following are some symptoms, which may or may not occur.

- drowsiness, dizziness
- pain or tenderness in the stomach

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps
- convulsions (fits)
- confusion
- unable to breathe.

While you are taking NOFLAM

Things you must do

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

If you are to be started on any new medicine, remind your doctor and pharmacist that you are taking NOFLAM.

Tell your doctor if you become pregnant while taking NOFLAM.

If you are going to have surgery, tell your surgeon or anaesthetist that you are taking NOFLAM.

Tell your doctor you are taking NOFLAM if you are going to have any laboratory tests. NOFLAM can affect the results of some tests.

If you get an infection while using NOFLAM, tell your doctor.

NOFLAM may hide some of the signs of an infection such as pain, fever, redness and swelling. You may mistakenly think that you are better or that it is not serious.

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.

Visit your doctor regularly so they can check on your progress.

Things you must not do

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

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

Do not use NOFLAM to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how NOFLAM affects you.

NOFLAM may cause dizziness, light-headedness, drowsiness or a spinning sensation (vertigo) in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Side effects

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

NOFLAM may have unwanted side effects in some 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.

Do not be alarmed by this list of possible 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), heartburn, indigestion
- constipation, diarrhoea, pain in the stomach
- dizziness, light-headedness, drowsiness
- headache
- buzzing or ringing in the ears
- sore or dry mouth or tongue (stomatitis)
- feeling thirsty

- loss of appetite
- aching muscles, muscle tenderness or weakness, not caused by exercise.

These are some of the more mild side effects.

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

- eye problems such as blurred vision or sore red eyes
- fast or irregular heartbeats, also called palpitations
- difficulty hearing, deafness
- bleeding or bruising more easily than normal, reddish-purple or blue-black blotches under the skin
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- depression (feelings of deep sadness and unworthiness)
- inability to sleep (insomnia), difficulty concentrating
- yellowing of the skin or eyes
- 'flu-like' symptoms.

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 notice any of the following:

- severe pain or tenderness in any part of the stomach
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea, or blood in the urine
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives or skin hypersensitivity
- fainting, seizures or fits, severe dizziness
- shooting pain from the stomach to the back (pancreatitis)

- pain or tightness in the chest.

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

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.

After taking NOFLAM

Storage

Keep your tablets in the original container and protect from light until it is time to take them.

If you take the medicine out of its container it may not keep well.

Keep NOFLAM tablets in a cool dry place where the temperature stays below 30°C. Protect from light.

Heat and dampness can destroy some medicines.

Do not store NOFLAM, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Keep NOFLAM 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 NOFLAM, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What NOFLAM looks like

NOFLAM 250 mg tablets are white round tablets. They are marked with "Naproxen 250" around the

circumference on one side and a score line on the other side.

NOFLAM 500 mg tablets are white capsule shaped tablets. They are marked "NP" score line "500" on one side and blank on the other side.

Ingredients

Each NOFLAM tablet contains the active ingredient naproxen.

NOFLAM 250 mg tablets contain 250 mg of naproxen.

NOFLAM 500 mg tablets contain 500 mg of naproxen.

NOFLAM 250 mg and 500 mg tablets also contain povidone, lactose, maize starch, sodium starch glycollate, talc, magnesium stearate and polysorbate 80.

NOFLAM does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:
Mylan New Zealand Ltd
P O Box 11183
Ellerslie
AUCKLAND

Telephone: (09) 579 2792

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