

Sonaflam

Naproxen 275 mg caplets

What is in this leaflet

This leaflet answers some common questions about Sonaflam. 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.

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 Sonaflam is taken for

Sonaflam is used for the temporary relief of pain and/or inflammation associated with muscular aches and pains, sprains and strains, backache, osteoarthritis, rheumatic pain, arthritis, headache, period pain and dental pain. Reduces fever.

Sonaflam contains the active ingredient naproxen sodium that 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 Sonaflam can relieve the symptoms of pain and inflammation, it will not cure your condition.

There is no evidence that Sonaflam is addictive.

Before you take Sonaflam

When you must not take it

Do not take Sonaflam if you have an allergy to:

- Any medicine containing naproxen such as Synflex[®], Naprosyn[®], Naxen[®], Noflam[®] or Naprogesic[®].
- Any of the other ingredients also contained in the tablet (these are listed at the end of this leaflet).

- Any other NSAID medicine. Examples of NSAIDs include aspirin, 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 Sonaflam, these symptoms may be severe.

Do not take Sonaflam if:

- aspirin or other NSAIDs have given you asthma, nasal polyps or rhinitis (hayfever 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
- you are pregnant or plan to become pregnant
- during the third trimester of pregnancy

Do not take Sonaflam if you are in your third trimester of pregnancy. It may affect your developing baby if you take it during this time.

Do not give Sonaflam 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 Sonaflam, talk to your doctor or pharmacist.

Before you start to take it

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

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

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

Do not take Sonaflam 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 or pharmacist if you are breastfeeding or plan to breast-feed.

Sonaflam passes into breast milk. Therefore, there is a possibility that the breast-fed baby may be affected. Your doctor will discuss the risks and benefits of taking Sonaflam 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 or pharmacist if you currently have an infection.

If you take Sonaflam 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.

Sonaflam can prolong bleeding.

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

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 Sonaflam 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 Sonaflam, 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 Sonaflam.

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

How to take Sonaflam

Follow all directions provided on the pack.

How much to take

Dosage for adults and children over the age of 12:

Take 1 or 2 caplets initially, then 1 caplet every 8 to 12 hours. Maximum 3 caplets in any 24 hour period. Do not exceed the maximum stated dose.

Do not give to children under 12 years of age except on doctor's advice.

How to take it

Swallow Sonaflam caplets whole with a glass of water.

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

When to take it

See above for details on frequency of administration.

How long to take it

Do not take Sonaflam for longer than a few days. If symptoms persist after a few days, seek advice from a healthcare professional. Long term use can be harmful and increases risk of heart attack, stroke or liver damage.

If you forget to take it

Resume taking the medication at the next scheduled time. Do not take a double dose to make up for the dose you missed.

While you are taking Sonaflam

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Sonaflam. If you are to be started on any new medicine, remind your doctor and pharmacist that you are taking Sonaflam.

Tell your doctor if you become pregnant while taking Sonaflam.

If you are going to have surgery, tell your surgeon or anaesthetist that you are taking Sonaflam. Tell your doctor you are taking Sonaflam if you are going to have any laboratory tests. Sonaflam can affect the results of some tests.

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

Sonaflam 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.

Things you must not do

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

Do not use Sonaflam 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 Sonaflam affects you.

Sonaflam 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.

In case of overdose

Immediately telephone your doctor or National Poisons Information Centre (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. 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.

Side Effects

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

Sonaflam 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
- 'flu-like' symptoms
- aching muscles, muscle tenderness or weakness, not caused by exercise

These are some of the milder 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-purplish 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
- severe or persistent headache

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
- flu-like symptoms with a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell
- enlarged lymph nodes known as eosinophilia.

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 using Sonaflam

Storage

Keep your caplets 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 Sonaflam caplets in a cool dry place where the temperature stays below 25°C. Protect from heat and moisture.

Heat and dampness can destroy some medicines. Do not store Sonaflam, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Keep Sonaflam 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

Discard medicine that still remains by returning any unused and/or expired medicine to a pharmacy.

Product description

What Sonaflam looks like

Blue coloured oval shaped film coated, biconvex tablets, plain on both sides.

Ingredients

Active ingredient:

- Naproxen sodium 275 mg

Inactive ingredients:

- Colloidal silicon dioxide
- Crospovidone
- Magnesium stearate
- Maize starch
- Opadry blue 03B50961
- Povidone
- Purified talc

Sonaflam contains no gluten or lactose.

If you want to know more

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

Who supplies this medicine

Sonaflam is supplied in New Zealand by:

Multichem NZ Ltd
Private Bag 93527
Takapuna
AUCKLAND

09 488 0330

Date of Preparation

This leaflet was prepared on 05 July 2024.