



Consumer Medicine Information

NAPROSYN[®]

Naproxen

250mg and 500mg tablets

750mg and 1000mg sustained release (SR) tablets

250mg and 500mg enteric coated (EC) tablets

25mg/mL suspension

What is in this leaflet

This leaflet answers some common questions about NAPROSYN tablets and suspension. NAPROSYN tablets are available in plain tablets, sustained release tablets and enteric coated tablets. Throughout this leaflet all three types of tablets are collectively referred to as 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 NAPROSYN tablets or suspension against the benefits expected 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 NAPROSYN is used for

NAPROSYN contains the active ingredient naproxen.

NAPROSYN 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 (eg. tennis elbow)
- gout (a disease with painful swollen joints)
- pain following surgery
- period pain

NAPROSYN 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.

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

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



NAPROSYN is not addictive.

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

Before you take NAPROSYN

When you must not take it

Do not take NAPROSYN if:

1. **you have an allergic reaction to NAPROSYN, or any ingredients listed at the end of this leaflet or you have had an allergic reaction to aspirin or any other NSAID medicine, including other naproxen containing medicines such as Synflex[®], Naxen[®] or Naprogesic[®].**

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 allergic to any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or 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 NAPROSYN, these symptoms may be severe.

2. **aspirin or other NSAIDs have given you asthma, or rhinitis (hayfever symptoms such as runny nose, stuffiness, watery eyes, sneezing, itchy nose, throat and eyes) in the past**
3. **you are vomiting blood or material that looks like coffee grounds**
4. **you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea**
5. **you have a peptic ulcer (i.e. stomach or duodenal ulcer)**
6. **you have a tendency to spontaneously bleed or bleed when incurring minor accidents (haemorrhagic diathesis)**
7. **you have liver disease**
8. **you have asthma**
9. **the package is torn or shows signs of tampering**
10. **the expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.
If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack.

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

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

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

Before you start to take it

Tell your doctor if:

1. you are pregnant or plan to become pregnant

NAPROSYN may make it more difficult to get pregnant and is not recommended in women trying to get pregnant. NAPROSYN may affect your developing baby if you take it during pregnancy. If it is necessary for you to take NAPROSYN, your doctor will discuss the risks and benefits of taking it during pregnancy.

Do not take NAPROSYN if you are in labour as it may harm you and/or affect the baby.

2. you are breast-feeding or plan to breast-feed

NAPROSYN passes into breast milk. Your doctor will discuss the risks and benefits of taking NAPROSYN if you are breast-feeding.

3. you have or have had any other health problems, especially the following:

- rhinitis, nasal polyps
- heartburn, indigestion, stomach ulcers or other stomach problems
- kidney or liver disease
- heart problems
- swelling of the hands, ankles or feet
- a tendency to bleed easily
- you are on a low sodium diet
- you have low salt levels in your blood
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

4. you currently have an infection

If you take NAPROSYN while you have an infection, the tablets or suspension 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.

5. you plan to have surgery

NAPROSYN can prolong bleeding.

6. you are elderly

Older people may require a lower dose.

7. you are allergic to any other medicines, foods, dyes or preservatives.

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

Taking other medicines

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

Some medicines may interfere with NAPROSYN. These medicines include:

- aspirin, salicylates or other NSAID medicines
- lithium (Lithicarb[®], Priadel[®]), a medicine used to treat some types of depression
- probenecid, a medicine used to treat gout
- frusemide (Diurin[®], Lasix[®]), a diuretic, also called fluid or water tablets.
- phenytoin (Dilantin[®]) a medicine used to treat epilepsy



- methotrexate (Methoblastin[®], Ledertrexate[®]), a medicine used to treat arthritis, kidney disease and some cancers
- warfarin (Coumadin[®], Marevan[®]), a medicine used to stop blood clots
- a group of medicines called β -blockers used to treat high blood pressure
- certain antibiotics called sulphonamides (Trisul[®], Apo-Sulfatrim[®], Salazopyrin[®])
- some medicines used to treat diabetes called sulphonylureas (Diamicon[®], Apo-Gliclazide[®], Minidiab[®], Gliben[®])

These medicines may be affected by NAPROSYN, 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 will advise you.

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

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

How to take NAPROSYN

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

They may differ from the information contained in this leaflet.

How much to take

Take NAPROSYN exactly as your doctor has prescribed.

Your doctor will tell you how many NAPROSYN tablets or how much suspension you or your child should take each day. Your doctor may give you a lower dose if you are older or have certain health problems.

Adults

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

Children

The usual dose for children over 5 years is 10mg/kg/day given as two divided doses at 12 hour intervals.

How to take it

Swallow NAPROSYN tablets whole with a glass of water.

Shake NAPROSYN suspension gently before use. Swallow NAPROSYN suspension followed by a glass of water if desired.

When to take it

Take NAPROSYN at about the same time each day.

It does not matter whether you take NAPROSYN with food or not. However, if you take NAPROSYN after food this may help reduce the possibility of an upset stomach.

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 NAPROSYN until your doctor tells you to stop.

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

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

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

For gout, NAPROSYN 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.

In case of 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 NAPROSYN. 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

Keep telephone numbers for these places handy.

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

While you are taking NAPROSYN

Things you must do

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

Tell your doctor if you become pregnant while taking NAPROSYN.



If you are going to have surgery, tell your doctor you are taking NAPROSYN.

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

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

NAPROSYN 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 or suspension are not helping your condition.

Be sure to keep all your appointments with your doctor so that your progress can be checked.

Things you must not do

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

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not use NAPROSYN 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 NAPROSYN affects you.

NAPROSYN may cause dizziness, light-headedness, drowsiness or a spinning sensation (vertigo) in some people. Make sure you know how you react to NAPROSYN before you drive a car, 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 NAPROSYN.

NAPROSYN helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious. You may need medical treatment if you get some of the side effects.

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
- spinning sensation (vertigo)
- headache
- buzzing or ringing in the ears

- sore or dry mouth or tongue (stomatitis)
- feeling thirsty
- skin eruptions, rash, itching, sweating

These are the more common side effects of NAPROSYN. Mostly these are mild.

Tell your doctor immediately, or go to your nearest Accident and Emergency Centre, if you notice any of the following:

- severe pain or tenderness in any part of the stomach
- eye problems such as blurred vision
- 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
- 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
- fainting, seizures or fits
- depression (feelings of deep sadness and unworthiness)
- inability to sleep (insomnia), difficulty concentrating
- yellowing of the skin or eyes
- shooting pain from the stomach to the back (pancreatitis)

These are serious side effects. You may need urgent medical attention. Serious side effects are 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, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking NAPROSYN

Storage

Keep your tablets or suspension 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 NAPROSYN tablets in a cool dry place where the temperature stays below 30°C.

Keep NAPROSYN suspension in a cool dry place where the temperature stays below 25°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Keep NAPROSYN 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.

Do not keep your tablets or suspension in the refrigerator.

Disposal

If your doctor tells you to stop taking NAPROSYN, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets or suspension that are left over.

Product description

Availability

NAPROSYN tablets come in 250mg and 500mg strengths. Both strengths come in blister packs of 100 tablets.

NAPROSYN EC tablets are available in 250mg and 500mg strengths. The 250mg tablet comes in a bottle of 120 tablets. The 500mg tablet comes in a bottle of 60 tablets.

NAPROSYN SR tablets are available in 750mg and 1000mg strengths. Both tablet strengths come in bottles of 90 tablets.

NAPROSYN suspension comes in a 25mg/mL strength. The suspension comes in a bottle containing 240mL.

What NAPROSYN looks like

Naprosyn 250mg Tablet

A round, yellow, uncoated tablet embossed 'NPR LE 250' on one face and a breakline on the other.

Naprosyn 500 mg Tablet

An oblong yellow tablet engraved 'NPR LE 500' on one face and a breakline on the other.

Naprosyn SR (sustained release) 750 mg Tablet

A capsule shaped, peach coloured tablet, 'NPR SR-750' on one side.

Naprosyn SR (sustained release) 1000 mg Tablet

A capsule shaped, peach coloured tablet, 'NPR SR-1000' on one side.

Naprosyn EC (enteric coated) 250mg Tablet

A flat, white, round tablet, inscribed 'NPR EC 250' on one side. The '250' is imprinted below NPR EC.

Naprosyn EC (enteric coated) 500mg Tablet

A capsule shaped, white tablet inscribed 'NPR EC 500' on one side. The '500' is imprinted below NPR EC.

Naprosyn 25mg/mL suspension

A white to off-white suspension containing evenly distributed particles, with a pineapple-orange odour.

Ingredients



Active ingredient - naproxen

- each NAPROSYN 250mg tablet contains 250 mg naproxen
- each NAPROSYN 500mg tablet contains 500 mg naproxen
- each NAPROSYN SR 750mg tablet contains 750mg naproxen
- each NAPROSYN SR 1000mg tablet contains 1000mg naproxen
- each NAPROSYN EC 250mg tablet contains 250mg naproxen
- each NAPROSYN EC 500mg tablet contains 500mg naproxen
- each bottle of NAPROSYN suspension contains 25mg of naproxen per mL

Inactive ingredients –

NAPROSYN 250mg and 500mg tablets

Povidone (K90), croscarmellose sodium (Type A), magnesium stearate, iron oxide, purified water.

NAPROSYN SR 750mg and 1000mg tablets

Hydroxypropyl methyl cellulose, magnesium stearate, FD&C Yellow No. 6, purified water.

NAPROSYN EC 250mg and 500mg tablets

Povidone (K90), croscarmellose sodium (Type A), magnesium stearate, purified water, methacrylic acid polymer (Type C), talc, sodium hydroxide, triethyl citrate, black printing ink.

NAPROSYN 25mg/mL suspension

Sucrose, sorbitol, sodium chloride, aluminium magnesium silicate, fumaric acid, methyl hydroxybenzoate, imitation orange flavour, imitation pineapple flavour, purified water.

Distributor

NAPROSYN is distributed by:

Roche Products (New Zealand) Limited
P O Box 12-492
Penrose
AUCKLAND

Telephone: (09) 633 0700

Toll Free: 0800 656 464

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