

NAPROSYN(R)

pronounced nap-row-sin

contains the active ingredient naproxen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NAPROSYN 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 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 NAPROSYN is used for

NAPROSYN belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAIDs).

NAPROSYN relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in the following:

- * in different types of arthritis including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
- * in muscle and bone injuries such as sprains, strains, lower back pain (lumbago), rheumatism and tendonitis, such as tennis elbow

- * swelling and pain after setting broken or dislocated bones
- * menstrual cramps (period pain)
- * headache, including migraines
- * following surgery
- * dental pain

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

Your doctor may have prescribed NAPROSYN for another reason.

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

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

NAPROSYN is not addictive.

Before you take NAPROSYN

When you must not take it

Do not take NAPROSYN if you have an allergy to:

- * **NAPROSYN or any ingredients listed at the end of this leaflet**
- * **aspirin or any other NSAID medicine**

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 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.

Do not take NAPROSYN if:

- 1. you are vomiting blood or material that looks like coffee grounds**
- 2. you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea**
- 3. you currently have a peptic ulcer (i.e. stomach or duodenal ulcer), or have had one before**
- 4. you are taking other medications which contain naproxen or naproxen sodium (e.g. Naprogesic(R), Anaprox(R) or Inza(R))**
- 5. you have severe heart failure**

Do not give NAPROSYN to a child under the age of 2 years

The safety and effectiveness of NAPROSYN in children under 2 years of age has not been established.

Do not take NAPROSYN if the package is torn or shows signs of tampering.

Do not take NAPROSYN if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

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

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- * any other medicines including aspirin or other NSAID medicines
- * any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant

NAPROSYN may impair fertility and is not recommended in women attempting to conceive. 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.

3. you are breast-feeding or intend to breast-feed

NAPROSYN passes into breast milk. The effect on the baby is not known.

4. you have or have had any medical conditions, especially the following:

- * heartburn, indigestion, stomach ulcers or other stomach problems
- * vomiting blood or bleeding from the back passage
- * bowel or intestinal problems such as ulcerative colitis
- * kidney or liver disease
- * heart failure
- * high blood pressure or heart problems
- * swelling of the ankles or feet
- * a tendency to bleed or other blood problems, such as anaemia

5. 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 it is not serious.

6. you plan to have surgery

NAPROSYN can prolong bleeding.

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

Taking other medicines

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

Some medicines may interfere with NAPROSYN. These include:

- * antacids, medicines used to treat indigestion and heartburn
- * aspirin, salicylates or other NSAID medicines
- * cholestyramine, a medicine used to treat high cholesterol levels
- * diuretics, also called fluid or water 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
- * medicines used to treat high blood pressure including ACE inhibitors, angiotensin receptor antagonists and beta-blockers
- * some medicines used to treat diabetes

- * sodium bicarbonate, a medicine used to treat stomach upset or ulcers
- * steroids, medicines used to treat inflammation
- * serotonin reuptake inhibitors, also known as SSRIs, medicines used to treat some types of depression
- * zidovudine, a medicine used to treat HIV infection

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 and pharmacist have 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.

Use in Children

There is no specific information available to recommend the use of NAPROSYN in children under 5 years.

Use in People Over 65 Years

Older people may be at more risk of developing stomach ulcers and hence your doctor may prescribe a lower dose.

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 to take each day. If you are an older patient, your doctor may give you a lower dose.

Sprains, strains and period pain

The recommended dose is 500 mg given initially, then 250 mg every 6 to 8 hours as needed. The total dose in one day should not exceed 1250 mg.

Migraine Headache

The recommended dose is 750 mg taken at the first sign of a migraine. An additional dose of 250 mg to 500 mg can be taken at least an hour after the initial dose, if required. The total dose in one day should not exceed 1250 mg.

Arthritis

The recommended dose is 375 mg to 1000 mg a day, divided in two doses.

For Juvenile Rheumatoid Arthritis, it is recommended that Naprosyn Suspension is given.

How to take it

Swallow NAPROSYN tablets whole with a glass of water or milk.

When to take it

Take the tablets during or immediately after food with a full glass of water or milk.

This may help reduce the possibility of an upset stomach.

How long to take NAPROSYN

Do not take NAPROSYN for longer than your doctor says.

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

For sprains and strains, NAPROSYN is usually only needed for a few days.

If you are taking 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.

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

If you forget to take NAPROSYN

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, ask your pharmacist for some hints.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital 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.

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

While you are taking NAPROSYN

Things you must do

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

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

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

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

If you are going to have any laboratory tests, tell your doctor that you are taking NAPROSYN.

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 are not helping your condition.

Things you must not do

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 tells you to.

Things to be careful of

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

As with other NSAID medicines, NAPROSYN may cause dizziness or light-headedness 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 if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

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 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.

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

These side effects of NAPROSYN 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, sore red eyes, itching
- * severe or persistent headache
- * fast or irregular heartbeats, also called palpitations
- * difficulty hearing, deafness
- * unusual weight gain, swelling of ankles or legs
- * severe skin rashes
- * 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 blood or what looks like coffee grounds
- * bleeding from back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- * difficulty breathing, wheezing or shortness of breath
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- * severe dizziness, spinning sensation
- * severe pain or tenderness in any part of the stomach
- * sudden or severe itching, skin rash and hives
- * pain, 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, 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 in the blister pack until it is time to take them.

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

Keep the tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store NAPROSYN, 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 in the refrigerator.

Disposal

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

Product description

Availability

NAPROSYN tablets are available in 250 mg and 500 mg strengths.

NAPROSYN comes in blister packs of 50.

NAPROSYN is also available as once-daily slow release tablets (Naprosyn SR(R)) and as a suspension (Naprosyn (R) Suspension)

What NAPROSYN tablets look like

NAPROSYN (250 mg) is a round yellow tablet marked "NPR LE 250" on one side.

NAPROSYN 500 is an oblong yellow tablet marked "NPR LE 500" on one side.

Ingredients

Active ingredient:

naproxen

- * each NAPROSYN tablet contains 250 mg naproxen
- * each NAPROSYN 500 tablet contains 500 mg naproxen.

Inactive ingredients:

- * povidone
- * croscarmellose sodium
- * iron oxide yellow (172)
- * magnesium stearate (470)

NAPROSYN tablets do not contain sucrose, tartrazine or any other azo dyes.

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

- * NAPROSYN tablets
AUST R 65247
- * NAPROSYN 500 tablets
AUST R 65246

This leaflet was prepared on 11 April 2008

Manufacturer

NAPROSYN is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

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Dee Why NSW 2099