

NAPROSYN(R) SUSPENSION

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 Suspension.

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 Suspension 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 SUSPENSION is used for

NAPROSYN Suspension contains the active ingredient naproxen.

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

- * different types of arthritis including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis

- * muscle and bone injuries such as sprains, strains, low 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 Suspension can relieve the symptoms of pain and inflammation, it will not cure your condition. NAPROSYN Suspension belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAIDs).

Your doctor may have prescribed NAPROSYN Suspension for another reason. Ask your doctor if you have any questions why NAPROSYN Suspension has been prescribed for you.

Use in children

NAPROSYN Suspension is recommended for use in children (over the age of 5) for the treatment of juvenile rheumatoid arthritis.

NAPROSYN Suspension is not addictive.

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

Before you take NAPROSYN SUSPENSION

When you must not take it

Do not take NAPROSYN Suspension if:

you have an allergy to:

- * **NAPROSYN Suspension 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 suspension, these symptoms may be severe.

Do not take NAPROSYN Suspension 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 have a peptic ulcer (i.e. stomach or duodenal ulcer), or have had peptic ulcers before**
4. **you are taking other medicines which contain naproxen or naproxen sodium (e.g. Naprogesic, Inza, Anaprox)**
5. **you have severe heart failure**

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

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

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

Do not take NAPROSYN Suspension 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 Suspension, 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 Suspension may impair fertility and is not recommended in women attempting to conceive.

NAPROSYN Suspension may affect your developing baby if you take it during pregnancy.

If it is necessary for you to take NAPROSYN Suspension, your doctor will discuss the risks and benefits of taking during pregnancy.

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

NAPROSYN Suspension 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
- * a tendency to bleed or other blood problems, such as anaemia
- * kidney or liver disease
- * heart failure
- * high blood pressure or heart problems
- * swelling of the ankles or feet.

5. you currently have an infection

If you take NAPROSYN Suspension while you have an infection, the 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 Suspension can prolong bleeding.

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

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 Suspension. 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
- * certain antibiotics called sulfonamides/quinolones
- * 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 Suspension, 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 may have more information on medicines

to be careful with or avoid while taking NAPROSYN Suspension.

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

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 SUSPENSION

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 Suspension exactly as your doctor has prescribed.

Your doctor will tell you how much NAPROSYN Suspension to take each day.

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

Sprains, strains and period pain

The recommended dose is 500 mg, followed by 250 mg every 6 to 8 hours, as needed. Total daily dose is 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 daily dose should not exceed 1250 mg.

Arthritis

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

Juvenile Rheumatoid Arthritis

The recommended dose for children 5 years and above is 10 mg/kg given in 2 equal divided doses (i.e. 5 mg/kg twice a day).

How to take it

Shake NAPROSYN Suspension gently before use.

Use a measuring cup or syringe to measure out the exact dose your doctor has prescribed.

Take NAPROSYN Suspension with a glass of water or milk.

When to take it

Take the suspension 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 it

Do not take NAPROSYN Suspension for longer than your doctor says.

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

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

If you are using NAPROSYN Suspension for arthritis, it will not cure your condition, but it should help to control the pain, swelling and stiffness. If you have arthritis, NAPROSYN Suspension 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 suspension 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 take a double dose to make up for the dose you have missed.

If you have trouble remembering to take your medicine, 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 casualty at your nearest hospital, if you think that you or anyone else may have taken too much NAPROSYN Suspension. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much NAPROSYN Suspension, 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 SUSPENSION

Things you must do

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

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

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

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

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

NAPROSYN Suspension can affect the results of some of these tests.

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

NAPROSYN Suspension 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 suspension is not helping your condition.

Things you must not do

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

Do not use NAPROSYN Suspension 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 Suspension affects you.

NAPROSYN Suspension may cause dizziness or light-headedness in some people. Make sure you know how you react to NAPROSYN Suspension 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 Suspension.

NAPROSYN Suspension 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, cramps
- * constipation, diarrhoea, pain in the stomach
- * loss of appetite
- * dizziness, light-headedness
- * drowsiness, sleepiness
- * headache
- * buzzing or ringing in the ears
- * feeling thirsty
- * aching muscles, muscle tenderness or weakness, not caused by exercise.

These are the more common side effects of NAPROSYN Suspension.

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

- * bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- * eye problems such as blurred vision
- * severe or persistent headache
- * fast or irregular heartbeats, also called palpitations
- * difficulty hearing, deafness
- * signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers

- * yellowing of the skin or eyes, also called jaundice
- * unusual weight gain, swelling of ankles or legs.

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

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 SUSPENSION

Storage

Keep your suspension in a cool dry place where the temperature stays below 25 degrees C. Do not store NAPROSYN Suspension, 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 Suspension 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 NAPROSYN Suspension, or the suspension has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

Availability

NAPROSYN Suspension is available as 25 mg/mL strength, in a bottle containing 474 mL.

NAPROSYN is also available in tablets containing 250 mg or 500 mg of naproxen.

What it looks like

NAPROSYN Suspension is a light orange suspension, with a pineapple-orange flavour. Particles readily re-suspend when shaken.

Ingredients

Active ingredient:

- * naproxen 25 mg/mL

Inactive ingredients:

- * sucrose
- * sorbitol
- * sodium chloride
- * magnesium aluminium silicate
- * fumaric acid
- * methyl hydroxybenzoate
- * imitation orange flavour
- * imitation pineapple flavour
- * the colour, Sunset Yellow FCF [110]
- * purified water

NAPROSYN Suspension does not contain, lactose, gluten, tartazine or any other azo dyes.

Manufacturer

NAPROSYN Suspension is distributed by:

Link Medical Products Pty Ltd

ACN 010 971 516

Level 1, Bridgepoint Centre

3 Brady Street

MOSMAN, NSW 2088

Customer enquiries: 1 800 233 950

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

Australian Registration Numbers:

- * AUST R 10055

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