

Naproxen Suspension

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Naproxen Suspension?

Naproxen Suspension contains the active ingredient naproxen. Naproxen Suspension is used to relieve pain and reduce inflammation (swelling, redness and soreness) in different types of arthritis, muscle and bone injuries, period pain, headaches, after surgery and dental pain. Children (over the age of 5) can use Naproxen Suspension to treat juvenile rheumatoid arthritis.

For more information, see Section [1. Why am I using Naproxen Suspension?](#) in the full CMI.

2. What should I know before I use Naproxen Suspension?

Do not use if you have ever had an allergic reaction to naproxen or any of the ingredients listed at the end of the CMI.

Do not use at all during the last three months of pregnancy. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Naproxen Suspension?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Naproxen Suspension and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Naproxen Suspension?

- Take Naproxen Suspension exactly as your doctor has told you.
- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use Naproxen Suspension?](#) in the full CMI.

5. What should I know while using Naproxen Suspension?

Things you should do	<ul style="list-style-type: none"> • If you become pregnant while taking Naproxen Suspension, tell your doctor immediately. • Remind any doctor, dentist, pharmacist or nurse you visit that you are using Naproxen Suspension.
Things you should not do	<ul style="list-style-type: none"> • Do not give Naproxen Suspension to anyone else, even if they have the same condition as you. • Do not use Naproxen Suspension to treat other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how Naproxen Suspension affects you. If dizziness and light-headedness occur, do not drive or use any machines or tools.
Drinking alcohol	<ul style="list-style-type: none"> • If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 25°C. Do not leave it in the car or on window sills. • Do not store in a bathroom or near a sink. Keep it where children can not reach it.

For more information, see Section [5. What should I know while using Naproxen Suspension?](#) in the full CMI.

6. Are there any side effects?

Common side effects include nausea, heartburn, indigestion, cramps, constipation, diarrhoea, stomach pain, loss of appetite, dizziness, headache, buzzing or ringing in the ears, feeling thirsty, muscle tenderness or weakness, bleeding or bruising and blurred vision. **Serious side effects** include not enough amniotic fluid in the womb during pregnancy, newborns with kidney failure, irregular heartbeats, difficulty hearing, fever, severe chills, sore throat, mouth ulcers, yellowing skin or eyes, weight gain, swelling ankles or legs, vomiting blood or coffee grounds materials, back passage bleeding, black stools or bloody diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Naproxen Suspension

Active ingredient: *naproxen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Naproxen Suspension. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Naproxen Suspension.**

Where to find information in this leaflet:

1. [Why am I using Naproxen Suspension?](#)
2. [What should I know before I use Naproxen Suspension?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Naproxen Suspension?](#)
5. [What should I know while using Naproxen Suspension?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Naproxen Suspension?

Naproxen Suspension contains the active ingredient naproxen. Naproxen Suspension belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAIDs).

Naproxen Suspension is used to relieve pain and reduce 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.

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

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Naproxen Suspension is not addictive.

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

2. What should I know before I use Naproxen Suspension?

Warnings

Do not use Naproxen Suspension if:

- you are in the third trimester of pregnancy (see Pregnancy and breastfeeding)
- you are allergic to naproxen, aspirin, other NSAID medicine, food, preservatives, dyes or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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) or have had peptic ulcers before
- you are taking other medicines which contain naproxen or naproxen sodium (e.g. Naprogesic, Inza, Anaprox)
- you have severe heart failure
- you have recently had or are about to have heart bypass surgery.

Check with your doctor if you have or have had:

- 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
- infection (signs include pain, fever)
- any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use at all during the last three months (third trimester) of pregnancy.

Naproxen Suspension may impair fertility and is not recommended in women attempting to conceive. It may increase the risk of miscarriage when used in early pregnancy and affect your developing baby if you take it during the latter part of pregnancy. If it is necessary for you to take Naproxen Suspension, your doctor will discuss the risks and benefits of taking this medicine during pregnancy. You may need to be closely monitored by your doctor. Discuss any questions you may have with your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in children

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Naproxen Suspension and affect how it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Naproxen Suspension.

4. How do I use Naproxen Suspension?

How much to take

For sprains, strains and period pain:

- The recommended dose is 500 mg, followed by 250 mg every 6 to 8 hours, as needed. The total daily dose is 1250 mg.

For 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.

For Arthritis:

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

For Juvenile Rheumatoid Arthritis:

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

Follow the instructions provided and use Naproxen Suspension until your doctor tells you to stop.

When to take Naproxen Suspension

- Naproxen Suspension should be taken during or immediately after food with a full glass of water or milk. This may help reduce the possibility of an upset stomach.

How to take Naproxen Suspension

- Shake Naproxen Suspension gently before use.
- Use a measuring cup or syringe to measure out the exact dose your doctor has prescribed.
- Take Naproxen Suspension with a glass of water or milk.

If you forget to use Naproxen Suspension

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 go back to taking your medicines as you would normally.

Do not take a double dose to make up for the dose you missed.

If you use too much Naproxen Suspension

If you think that you have used too much Naproxen Suspension, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Naproxen Suspension?

Things you should do

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

If you are going to have surgery or have any laboratory tests, tell your doctor you are taking Naproxen Suspension.

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

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Call your doctor straight away if you:

- have fever, skin rash, swelling of the face
- become pregnant while taking Naproxen Suspension
- feel the suspension is not helping your condition.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Naproxen Suspension.

Things you should not do

- Do not give Naproxen Suspension to anyone else, even if they have the same condition as you.
- Do not use Naproxen Suspension to treat other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Naproxen Suspension affects you.

Naproxen Suspension may cause dizziness and light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make dizziness or lightheadedness worse.

Looking after your medicine

- Store below 25°C

Follow the instructions on the label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking Naproxen Suspension or the expiry date has passed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Ear related:</p> <ul style="list-style-type: none"> • buzzing or ringing in the ears <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • stomach upset including nausea (feeling sick), heartburn, indigestion, cramps • constipation, diarrhoea, pain in the stomach • loss of appetite <p>Mouth related:</p> <ul style="list-style-type: none"> • feeling thirsty <p>Musculoskeletal:</p> <ul style="list-style-type: none"> • aching muscles, muscle tenderness or weakness, not caused by exercise. <p>Nervous system:</p> <ul style="list-style-type: none"> • dizziness, light-headedness • drowsiness, sleepiness • headache 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Cardiovascular:</p> <ul style="list-style-type: none"> fast or irregular heartbeats, also called palpitations <p>Ear related:</p> <ul style="list-style-type: none"> difficulty hearing, deafness <p>Eye related:</p> <ul style="list-style-type: none"> eye problems such as blurred vision yellowing of the eyes also called jaundice <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> pain or tightness in the chest 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 unusual weight gain <p>Nervous system:</p> <ul style="list-style-type: none"> severe dizziness, spinning sensation fainting, seizures or fits severe or persistent headache <p>Respiratory related:</p> <ul style="list-style-type: none"> difficulty breathing, wheezing or shortness of breath <p>Pregnancy related:</p> <ul style="list-style-type: none"> not enough amniotic fluid in the womb during pregnancy newborns with kidney failure <p>Skin related:</p> <ul style="list-style-type: none"> sudden or severe itching, skin rash, hives bleeding or bruising more easily than normal, reddish or purplish blotches under the skin yellowing of the skin also called jaundice <p>Signs of serious infections, such as:</p> <ul style="list-style-type: none"> swollen lymph glands 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing fever, severe chills, sore throat or mouth ulcers swelling of ankles or legs 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Naproxen Suspension contains

Active ingredient (main ingredient)	naproxen
Other ingredients (inactive ingredients)	sucrose sorbitol sodium chloride aluminium magnesium silicate fumaric acid methyl hydroxybenzoate imitation orange flavour imitation pineapple flavour the colour sunset yellow FCF purified water

Naproxen Suspension contains sugars (as sucrose).

Naproxen Suspension contains sorbitol. Sorbitol may have a laxative effect or cause diarrhoea.

Do not take this medicine if you are allergic to any of these ingredients.

What Naproxen Suspension looks like

Naproxen Suspension is a light orange suspension, with a pineapple-orange flavour. Particles readily re-suspend when shaken. (AUST R 196596).

Do not take Naproxen Suspension if the bottle is damaged or shows signs of tampering.

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

Who distributes Naproxen Suspension

Naproxen Suspension is supplied in Australia by:

Phebra Pty Ltd
19 Orion Road, Lane Cove West,
NSW 2066, Australia.
Telephone: 1800 720 020

This leaflet was prepared in June 2021.

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