

# PROXEN SR®

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## 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.

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### 1. Why am I using PROXEN SR?

PROXEN SR contains the active ingredient naproxen. PROXEN SR is used to relieve pain and reduces inflammation (swelling, redness and soreness) that may occur in different types of arthritis including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. For more information, see Section [1. Why am I using PROXEN SR?](#) in the full CMI.

### 2. What should I know before I use PROXEN SR?

Do not use if you have ever had an allergic reaction to naproxen, aspirin or any other NSAID medicines, or any of the ingredients listed at the end of the CMI. **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 PROXEN SR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PROXEN SR 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 PROXEN SR?

- Your doctor will tell you how many PROXEN SR tablets to take each day. The usual dose is one tablet once a day.
- More instructions can be found in Section [4. How do I use PROXEN SR?](#) in the full CMI.

### 5. What should I know while using PROXEN SR?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using PROXEN SR.
- Tell your doctor if you get an infection while using PROXEN SR.

	<ul style="list-style-type: none"> <li>• Tell your doctor if you feel the tablets are not helping your condition.</li> <li>• Call your doctor straight away if you become pregnant while taking PROXEN SR.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not give PROXEN SR to anyone else, even if they have the same condition as you.</li> <li>• Do not use PROXEN SR to treat other complaints unless your doctor tells you to.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how PROXEN SR affects you.</li> <li>• PROXEN SR may cause dizziness or light-headedness in some people. If this occurs, do not drive.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol. If you drink alcohol, dizziness or light-headedness may be worse.</li> </ul>

### **Looking after your medicine**

- Keep the tablets in a cool dry place away from moisture, heat or sunlight. Store below 30°C.
- Do not keep your tablets in the refrigerator.

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

## **6. Are there any side effects?**

Tell your doctor immediately if you notice any of the following serious side effects: difficulty hearing, deafness, severe or persistent headache, yellowing of the skin, bleeding or bruising more easily than normal, reddish or purplish blotches under the skin, fast or irregular heartbeats, eye problems such as blurred vision, yellowing of the eyes, unusual weight gain, swelling of ankles or legs. Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following very serious side effects: vomiting blood or what looks like coffee grounds, bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea, severe dizziness, spinning sensation, severe pain or tenderness in any part of the stomach, swelling of the face, lips or tongue which may cause difficulty in swallowing, difficulty breathing, wheezing or shortness of breath, sudden or severe itching, skin rash or hives, fainting, seizures or fits, pain or tightness in the chest,

flu-like symptoms with a rash on the face then an extended rash with a high temperature and enlarged lymph nodes. 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.

# PROXEN SR®

**Active ingredient:** naproxen

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using PROXEN SR. **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 PROXEN SR.**

**Where to find information in this leaflet:**

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

## 1. Why am I using PROXEN SR?

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

**PROXEN SR is used to relieve pain and reduces inflammation (swelling, redness and soreness) that may occur in different types of arthritis including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.**

As the active ingredient in PROXEN SR, is released slowly into the bloodstream during the day, the tablets are not suitable for use in conditions where rapid pain relief is needed e.g. migraine attacks or in conditions needing only short term pain relief.

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

Your doctor may have prescribed PROXEN SR for another reason.

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

## **2. What should I know before I use PROXEN SR?**

### **Warnings**

#### **Do not use PROXEN SR if:**

- you are allergic to naproxen, aspirin or any other NSAID medicine, or any of the ingredients listed at the end of this leaflet. 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 doctor or pharmacist. If you are allergic to aspirin or NSAID medicines and use PROXEN SR, these symptoms may be severe. 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

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 currently have a peptic ulcer (i.e. stomach or duodenal ulcer), or have had peptic ulcers before
- you have severe liver disease
- you have recently had or are about to have heart bypass surgery
- you are taking other medications which contain naproxen or naproxen sodium (e.g. Naprosyn<sup>®</sup>, Naprogesic<sup>®</sup>, Anaprox<sup>®</sup> or Inza<sup>®</sup>)
- you have severe heart failure

**Do not give PROXEN SR to a child under the age of 2 years.** The safety and effectiveness of PROXEN SR in children under 2 years of age has not been established.

If you are not sure if you should start taking PROXEN SR, contact your doctor.

### **Check with your doctor if you:**

- have allergies to any other substances, such as foods, preservatives or dyes
- 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
  - currently have an infection. If you take PROXEN SR while you have an infection, the signs may be hidden (e.g. pain, fever). This may make you think, mistakenly, that you are better or that it is not serious.
- you plan to have surgery. PROXEN SR can prolong bleeding.

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

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**

**Tell your doctor if you are pregnant or intend to become pregnant.**

PROXEN SR may affect your developing baby if you take it during pregnancy. If it is necessary for you to take PROXEN SR, your doctor will discuss the risks and benefits of taking it during pregnancy.

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

**Tell your doctor if you are breast-feeding or intend to breast-feed.**

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

## **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 PROXEN SR and affect how it works. These include:**

- antacids, medicines used to treat heartburn and indigestion
- 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
- serotonin reuptake inhibitors, also known as SSRIs, medicines used to treat some types of depression
- steroids, medicines used to treat inflammation
- zidovudine, a medicine used to treat HIV infection
- sodium bicarbonate, a medicine used to treat stomach upset or ulcers
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These medicines may be affected by PROXEN SR, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

## **4. How do I use PROXEN SR?**

### **How much to take**

- Take PROXEN SR exactly as your doctor has prescribed.
- Your doctor will tell you how many PROXEN SR tablets to take each day. The usual dose is one tablet once a day.
- Follow the instructions provided and use PROXEN SR until your doctor tells you to stop. They may differ from the information contained in this leaflet.

### **How to take PROXEN SR**

- Swallow PROXEN SR whole with a glass of water or milk. Do not chew them.

### **When to take PROXEN SR**

- Take the tablets with or straight after food with a full glass of water or milk. This may help reduce the possibility of an upset stomach.

## **How long to take PROXEN SR**

- Do not take PROXEN SR for longer than your doctor says.
- If you are taking PROXEN SR for arthritis, it will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis, PROXEN SR should be taken every day for as long as your doctor prescribes.
- Ask your doctor if you are not sure how long to take PROXEN SR for.

## **If you forget to take PROXEN SR**

**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 missed.**

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you use too much PROXEN SR**

If you take too much PROXEN SR, you may experience drowsiness, pain or tenderness in the stomach, stomach upset including nausea (feeling sick), vomiting,

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heartburn, indigestion or cramps. If you think that you have used too much PROXEN SR, 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 PROXEN SR?**

### **Things you should do**

- Ask your doctor or pharmacist before you start taking any new medicines.
- Tell your doctor you are taking PROXEN SR if you are going to have surgery.
- Tell you doctor or pharmacist before you start taking any new medicines.
- Tell your doctor you are taking PROXEN SR if you are going to have any laboratory tests. PROXEN SR can affect the results of some of these tests.
- Tell your doctor if you get an infection while using PROXEN SR. PROXEN SR 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.

### **Call your doctor straight away if you:**

- become pregnant while taking PROXEN SR.

Remind any doctor, dentist or pharmacist you visit that you are using PROXEN SR.

### **Things you should not do**

- Do not give PROXEN SR to anyone else, even if they have the same condition as you.
- Do not use PROXEN SR 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 PROXEN SR affects you.**

As with other NSAID medicines, PROXEN SR may cause dizziness or light-headedness in some people. If this occurs do not drive.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

If you drink alcohol, dizziness or light-headedness may be worse.

## **Looking after your medicine**

- 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°C.
- Do not keep your tablets in the refrigerator.

Follow the instructions in the carton 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.**

## **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. PROXEN SR helps most people with pain due to inflammation, but it may have unwanted side effects in a few people.

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.

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

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● <b>Gut related:</b></li><li>● stomach upset including nausea (feeling sick), heartburn, indigestion</li><li>● loss of appetite</li><li>● constipation, diarrhoea, pain in the stomach</li><li>●</li><li>● <b>Head related:</b></li><li>● dizziness, light-headedness</li></ul>	Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects of PROXEN SR are usually mild.

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● headache, drowsiness</li> <li>● buzzing or ringing in the ears</li> <li>● dry mouth</li> <li>● <b>Muscle related:</b></li> <li>● aching muscles, muscle tenderness or weakness, not caused by exercise</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● <b>Head related:</b></li> <li>● difficulty hearing, deafness</li> <li>● severe or persistent headache</li> <li>● <b>Skin related:</b></li> <li>● yellowing of the skin</li> <li>●</li> <li>● <b>Bleeding related:</b></li> <li>● bleeding or bruising more easily than normal, reddish or purplish blotches under the skin</li> </ul>	<p><b>Tell your doctor immediately if you notice any of these serious side effects. You may need urgent medical attention. Serious side effects are rare.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>● fast or irregular heartbeats, also called palpitations</li> </ul> <p>● <b>Eye related:</b></p> <ul style="list-style-type: none"> <li>● eye problems such as blurred vision</li> <li>● yellowing of the eyes</li> </ul> <p>● <b>Other:</b></p> <ul style="list-style-type: none"> <li>● unusual weight gain, swelling of ankles or legs</li> </ul>	

## **Very serious side effects**

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Gastrointestinal or gut related:</b></p> <ul style="list-style-type: none"> <li>● vomiting blood or what looks like coffee grounds</li> <li>● bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation. These</b></p>

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Head related:</b></p> <ul style="list-style-type: none"> <li>● severe dizziness, spinning sensation</li> </ul> <p>● <b>Pain related:</b></p> <ul style="list-style-type: none"> <li>● severe pain or tenderness in any part of the stomach</li> </ul> <p>● <b>Allergic reaction related:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing</li> <li>● difficulty breathing, wheezing or shortness of breath</li> <li>● sudden or severe itching, skin rash or hives</li> <li>● fainting, seizures or fits</li> <li>● pain or tightness in the chest</li> <li>● 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</li> </ul>	<p><b>very serious side effects are rare.</b></p>

<b>Very serious side effects</b>	<b>What to do</b>
tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.	

**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](http://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.

PROXEN SR is not addictive.

## What PROXEN SR contains

<b>Active ingredient (main ingredient)</b>	each PROXEN SR 750 tablet contains 750 mg naproxen  each PROXEN SR 1000 tablet contains 1000 mg naproxen.
<b>Other ingredients (inactive ingredients)</b>	hypromellose magnesium stearate [470] the colour, Sunset Yellow
<b>Potential allergens</b>	PROXEN SR tablets does not contain sucrose, tartrazine or any other azo dyes.

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

## What PROXEN SR looks like

PROXEN SR tablets are available in two strengths.

PROXEN SR 750 is a peach coloured oval tablet marked "NPR SR-750" on one side (Aust R 259113).

PROXEN SR 1000 is a peach coloured oval tablet marked "NPR SR-1000" on one side (Aust R 259112).

PROXEN SR 750 and 1000 come in blister packs of 28 tablets.

## **Who distributes PROXEN SR**

PROXEN SR is supplied in Australia by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough VIC 3173

Australia

Customer enquiries: 1 800 899 005

Sponsor:

Atnahs Pharma Australia Pty Ltd

Level 10

10 Shelley Street,

SYDNEY, NSW, 2000, Australia

This leaflet was prepared in August 2021.