

PROXEN SR®

contains the active ingredient naproxen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PROXEN SR 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 PROXEN SR tablets 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 PROXEN SR is used for

PROXEN SR belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

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

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

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.

Your doctor may have prescribed PROXEN SR for another purpose.

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

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

PROXEN SR is not addictive.

Before you take PROXEN SR

When you must not take it

Do not take PROXEN SR if you have an allergy to:

- **PROXEN SR 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 PROXEN SR, these symptoms may be severe.

Do not take PROXEN SR 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 have severe liver disease**
- 5. you have recently had or are about to have heart bypass surgery**
- 6. you are taking other medications which contain naproxen or naproxen sodium (e.g. Naprosyn SR[®], Naprogesic[®], Anaprox[®], Crysanal[®] or Inza[®])**
- 7. 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 the age of 2 years has not been established.

Do not take PROXEN SR if the packaging is torn or shows signs of tampering.

Do not take PROXEN SR 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 PROXEN SR, contact 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

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

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

PROXEN SR 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 PROXEN SR while you have an infection, the tablets may hide some of the signs of an infection (eg pain, fever). This may make you think, mistakenly, that you are better or that it is not serious.

6. 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.

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 PROXEN SR. 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
- selective 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

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.

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

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

How to take PROXEN SR

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

They may differ from the information contained in this leaflet

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.

How to take it

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

When to take it

Take the tablets with or straight after food with a full glass of water.

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 go back to taking it as you would normally.

Do not take a double a dose to make up for the dose that you 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 Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much PROXEN SR. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are using PROXEN SR

Things you must do

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

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

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 PROXEN SR.

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

PROXEN SR can affect the results of some of these tests.

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

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.

Things you must 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.

Things to be careful of

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

As with other NSAID medicines, PROXEN SR may cause dizziness or light-headedness in some people. Make sure you know how you react to PROXEN SR 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 PROXEN SR.

PROXEN SR helps most people 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
- constipation, diarrhoea, pain in the stomach
- loss of appetite
- dizziness, light-headedness
- headache, drowsiness
- buzzing or ringing in the ears
- dry mouth
- aching muscles, muscle tenderness or weakness, not caused by exercise

These side effects of PROXEN SR are usually mild.

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
- unusual weight gain, swelling of ankles or legs
- 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 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
- difficulty breathing, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- 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 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 using PROXEN SR

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°C.

Do not store PROXEN SR 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 it 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 PROXEN SR, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

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.

PROXEN SR 1000 is a peach coloured oval tablet marked "NPR SR 1000" on one side.

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

Ingredients

Active ingredient:

naproxen

- each PROXEN SR 750 tablet contains 750 mg naproxen
- each PROXEN SR 1000 tablet contains 1000 mg naproxen.

Inactive ingredients:

- hypromellose
- magnesium stearate [470]
- the colour, Sunset Yellow

PROXEN SR does not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Sponsor

Atnahs Pharma Australia Pty Ltd

Level 10

10 Shelley Street,

SYDNEY, NSW, 2000, Australia

Supplier

PROXEN SR is supplied in Australia by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough VIC 3173

Australia

Customer enquiries: 1 800 899 005

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

Australian Registration Numbers:

- PROXEN SR 750 tablets
AUST R 259113
- PROXEN SR 1000 tablets
AUST R 259112

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