

NAPROSYN®
Pain Relief

250 mg gastro-resistant tablets
Naproxen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a pharmacist or doctor if your symptoms do not improve after 3 days or if they worsen.

What is in this leaflet

1. What Naprosyn Pain Relief is and what it is used for
2. What you need to know before you take Naprosyn Pain Relief
3. How to take Naprosyn Pain Relief
4. Possible side effects
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1. What Naprosyn Pain Relief is and what it is used for

Naprosyn Pain Relief contains a medicine called naproxen. This is a 'Non Steroidal Anti Inflammatory Drug' (NSAID).

Naproxen can reduce pain, swelling, redness and heat (inflammation).

Naprosyn Pain Relief is used for the short-term relief of muscle and joint pain, sprains, strains, inflammation caused by sporting injuries, lower back pain, neck pain or pain in the wrists or feet.

2. What you need to know before you take Naprosyn Pain Relief

Do not take Naprosyn Pain Relief if you:

- are **allergic (hypersensitive) to naproxen, naproxen sodium** or any of the other ingredients of Naprosyn Pain Relief (listed in section 6)
- are **allergic to aspirin, or other NSAIDs**, or you have ever had asthma, runny nose, swelling of the skin or rash when taking these medicines
- have or have ever had **stomach or duodenal (gut) ulcers, bleeding in the stomach or intestines** (gastrointestinal bleeding)
- have previously experienced **bleeding or perforation in your stomach** while taking **NSAIDs**
- are taking other NSAID painkillers, or aspirin (see section 2 'Other medicines and Naprosyn Pain Relief').
- are taking any medicines which could increase the risk of bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs), or anti-platelet agents such as aspirin (see section 2 'Other medicines and Naprosyn Pain Relief')
- have a **severe kidney, liver or heart condition**

- are in the **last three months of pregnancy.**

Do not take Naprosyn Pain Relief if any of the above apply to you. If you are not sure, talk to your pharmacist or doctor before taking Naprosyn Pain Relief.

Warnings and precautions

Medicines such as naproxen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of use.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Talk to your pharmacist or doctor before taking Naprosyn Pain Relief if you:

- have **asthma**, or **rhinitis** (a runny, itchy or blocked nose and sneezing) or lumps in your nose (**nasal polyps**)
- have **kidney** or **liver problems**
- have any **blood clotting disorders**
- have or have ever had **high blood pressure**, a **stroke** or any **heart problems**
- have **high cholesterol**, **diabetes** or you **smoke**
- have **mixed connective tissue disease** or an **autoimmune condition**, such as 'systemic lupus erythematosus' (SLE), which causes joint pain, skin rashes and fever
- have **ulcerative colitis** or **Crohn's disease** (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).

If any of the above apply to you, or if you are not sure, talk to your pharmacist or doctor before you take Naprosyn Pain Relief.

Serious skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with naproxen.

Stop taking this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents

Naprosyn Pain Relief is not recommended for use in children and adolescents under 18 years of age.

Other medicines and Naprosyn Pain Relief

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your pharmacist or doctor if you are taking:

- other pain killers, e.g. aspirin, ibuprofen, diclofenac, and paracetamol
- medicines used to prevent your blood clotting, e.g. aspirin/ acetylsalicylic acid, warfarin, heparin, or clopidogrel
- hydantoines (to treat epilepsy), e.g. phenytoin
- sulfonamide medicines, such as hydrochlorothiazide, acetazolamide, indapamide and sulfonamide antibiotics (used to treat infections)
- a sulfonylurea (to treat diabetes), e.g. glimepiride or glipizide
- ACE inhibitors or any other medicine for high blood pressure such as cilazapril, enalapril or propranolol
- angiotensin-II receptor antagonists, e.g. candesartan, eprosartan or losartan

- diuretics (water tablets), e.g. furosemide
- cardiac glycosides such as digoxin (for heart failure)
- corticosteroids e.g. hydrocortisone, prednisolone and dexamethasone
- quinolone antibiotics (used to treat bacterial infections) e.g. ciprofloxacin or moxifloxacin
- lithium (used to treat certain mental health conditions)
- selective serotonin reuptake inhibitors (SSRIs) (used to treat depression) e.g. fluoxetine or citalopram
- probenecid (used for gout)
- methotrexate (used to treat skin problems, arthritis or cancer)
- ciclosporin or tacrolimus (used to suppress the immune system)
- zidovudine (used to treat AIDS and HIV infections)
- antacids (for heartburn)
- colestyramine (for high cholesterol)
- mifepristone (used to end pregnancy) - naproxen should not be taken within 8-12 days of taking mifepristone.

If any of the above apply to you, or if you are not sure, talk to your pharmacist or doctor before you take Naprosyn Pain Relief.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine
- **You should not take Naprosyn Pain Relief during the first 6 months of pregnancy** unless absolutely necessary and advised by your doctor. If you need treatment during this period or while

you are trying to get pregnant, the lowest dose for the shortest time possible should be used

- If taken for more than a few days from 20 weeks of pregnancy onward, Naprosyn Pain Relief can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby.
If you need treatment for longer than a few days, your doctor may recommend additional monitoring
- **Do not take Naprosyn Pain Relief if you are in the last 3 months of pregnancy**, as it could harm your unborn baby or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect you and your baby's tendency to bleed and cause labour to be later or longer than expected
- You should avoid taking Naprosyn Pain Relief if you are breastfeeding
- Naproxen may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

You may experience dizziness, drowsiness, spinning sensation (vertigo), difficulty in sleeping, depression or problems with your eyesight when taking naproxen. If you are affected do not drive or operate machinery.

Information on sodium content

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

XXXX Pharma code
READ DIRECTION →

420 mm

148 mm

3. How to take Naprosyn Pain Relief

This medicine is for short-term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor has told you. Check with your pharmacist or doctor if you are not sure.

Swallow the tablets whole with a little water, with or after food. The tablet is coated with a gastro-resistant coating. This allows the tablet to pass undissolved through the stomach into the small intestine, where the naproxen is released from the tablet. Do not crush or chew the tablets.

Adults aged 18 to 50 years

First day of treatment

Initially take two tablets (500 mg) then if needed, one tablet (250 mg) after 6-8 hours.

Second and third day of treatment

If needed, take one tablet (250 mg) every 6-8 hours. Do not take more than the maximum dose of three tablets a day.

Do not take for longer than 3 days unless your doctor tells you to. Check with you doctor or pharmacist if you are not sure.

If your symptoms do not improve or worsen talk to your pharmacist or doctor.

Naprosyn Pain Relief is not recommended for those over 50 years of age.

Make sure that you drink plenty of water (stay well hydrated) when you are taking Naprosyn Pain Relief. This is particularly important for people who have problems with their kidneys.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Medicines such as naproxen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with higher doses and prolonged (longer term) treatment.

Stop taking Naprosyn Pain Relief and seek urgent medical advice if you experience any of the following side effects:

- An **allergic reaction**: swelling of the face, mouth, tongue, airways or body; difficulty breathing or wheezing, coughing up blood; skin reactions including hives (pale/red raised skin with severe itching), itchy skin rash, blood spots, bruising or discolouring of the skin, raised purple rashes, red skin patches, bumpy rashes, blisters, dermatitis (skin shedding, itching, swelling)

5. How to store Naprosyn Pain Relief

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Store in original package in order to protect from light. Store below 30°C.
- Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Naprosyn Pain Relief contains

The active substance in Naprosyn Pain Relief 250 mg Tablets is naproxen. Each tablet contains 250 mg (milligrams) of naproxen.

The other ingredients in the tablet are povidone, magnesium stearate, water, croscarmellose sodium, methacrylic acid – ethyl acrylate copolymer, purified talc, sodium hydroxide, triethyl citrate, iron oxide black, shellac, propylene glycol, isopropyl alcohol, ammonium hydroxide and N-butyl alcohol.

What Naprosyn Pain Relief looks like and contents of the pack

Naprosyn Pain Relief 250 mg Tablets are round, white, and marked with NPR EC 250 on one side.

Naprosyn Pain Relief Tablets are supplied in blister packs containing 9 tablets.

Marketing Authorisation Holder

Maxwellia Ltd, Alderley Park, Alderley Edge, SK10 4TG, United Kingdom.

Manufacturer

Misom Labs Ltd, Malta Life Sciences Park, LS2.01.06 Industrial Estate, San Gwann, SGN 3000, Malta.

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Other side effects (not known, frequency cannot be estimated from the available data):

- A distinctive **cutaneous allergic reaction** known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching
- **Severe skin rash** with flushing, blisters or ulcers (Stevens-Johnson syndrome); a severe rash with reddening, peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis); blistering of skin when exposed to sunlight (pseudoporphyria); widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (drug reaction with eosinophilia and systemic symptoms, which is also known as DRESS). See also section 2
- **Heart attack**: signs include chest pain which may spread to your neck and shoulders and down your left arm
- **Stroke**: signs include muscle weakness and numbness. This may only be on one side of your body. A suddenly altered sense of smell, taste, hearing or vision, or confusion
- **Serious stomach problems**: ulcer or inflammation in the stomach or gut (causing indigestion, heartburn, pains in your stomach, feeling or being sick); worsening of colitis and Crohn’s disease (pain, diarrhoea, vomiting, weight loss); black tarry looking stools (signs of bleeding and perforation of the stomach and intestines); vomiting any blood or dark particles that look like coffee grounds; pancreatitis (causing fever, stomach pain, sickness)
- Sudden shortness of breath, chest pain, nausea, these could be signs of **hyperkalaemia**
- **Meningitis**: symptoms include a stiff neck, headache, feeling or being sick, fever, sensitivity to bright light and confusion. This is most likely in

people with autoimmune conditions such as ‘systemic lupus erythematosus’ (SLE)

- **Liver problems** including yellowing of the skin or whites of your eyes (**jaundice**); feeling tired, loss of appetite, feeling or being sick, pale coloured stools (**hepatitis** shown in blood tests).

thirst, fever, feeling tired or generally unwell

- muscle pain or weakness, sweating, hair loss
- problems for women in getting pregnant
- ‘Systemic lupus erythematosus’ (SLE) – signs include fever, rash, problems with your kidneys and joint pain.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

heartburn, indigestion, abdominal discomfort or pain, feeling sick or being sick, constipation, diarrhoea, wind

- changes to the number and types of blood cells causing illness such as anaemia or an increased risk of infections
- difficulty sleeping (insomnia), abnormal dreams, depression, confusion, or hallucinations (seeing, hearing, or believing things which are not real)
- fits or seizures, dizziness, headache, light-headedness, or drowsiness
- pins and needles or numbness of your hands and feet
- difficulty concentrating or forgetfulness
- changes to your eyesight, eye pain
- changes to your hearing, including ringing in your ears (tinnitus) or hearing loss, or spinning sensation (vertigo)
- swelling of your hands, feet, or legs (oedema)
- a fluttering feeling in your heart (palpitations), or high blood pressure
- problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain
- difficulty breathing, wheezing or coughing
- pneumonia or swelling of your lungs
- blood in your water (urine) or kidney problems

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