

PACKAGE LEAFLET: INFORMATION FOR THE USER

Naproxen 500 mg 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.
- If you have any further questions, ask your doctor or pharmacist.
- **This medicine has been prescribed for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

WHAT IS IN THIS LEAFLET

1. What Naproxen Tablets are and what they are used for
2. What you need to know before you take Naproxen Tablets
3. How to take Naproxen Tablets
4. Possible side effects
5. How to store Naproxen Tablets
6. Contents of the pack and other information

1. WHAT NAPROXEN TABLETS ARE AND WHAT THEY ARE USED FOR

Naproxen is one of a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Naproxen reduces inflammation and pain in the joints and muscles.

Naproxen is used for treatment of:

- rheumatoid arthritis or other rheumatic or musculoskeletal disorders (ailments that cause pain and stiffness in muscles, bones and joints)
- women, while having period pain
- acute gout

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NAPROXEN TABLETS

DO NOT take Naproxen Tablets

- if you are allergic to naproxen or any of the other ingredients of Naproxen Tablets (listed in section 6)
- if you are allergic to or have ever had a reaction to aspirin or another NSAID (non-steroidal anti-inflammatory drug) such as ibuprofen or meloxicam, or you have developed signs of asthma (wheezing), runny nose, lumps in your nose or swelling of the skin or rash when taking these medicines
- if you have a stomach ulcer or if you often get stomach ulcers or bleeding
- if you have a duodenal ulcer (in the first part of the small intestine) or if you often get duodenal ulcers
- if you have serious liver or kidney disease
- if you are suffering or have ever suffered two or more episodes of ulcers or bleeding from the stomach or intestines while taking NSAIDs
- if you are more than 6 months pregnant or if you are breast-feeding (see section 2 "Pregnancy and breast-feeding")
- if you have insufficient strength of the heart to pump blood (severe heart failure)

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

Warnings and precautions:

Talk to your doctor or pharmacist before taking Naproxen Tablets if you:

- have heart problems, have previously had a 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)
- if you are an older person
- have problems with how your blood clots
- have ever had bronchial asthma or allergies (like hayfever) or you have had swelling of the face, lips, eyes or tongue in the past
- suffer from localised swelling, high blood pressure or heart failure
- have too much fat (lipid) in your blood (hyperlipidaemia)
- have problems with your kidneys or liver
- have an autoimmune condition, such as 'systemic lupus erythematosus' that causes joint pain, skin rashes and fever
- have colitis or Crohn's disease, the symptoms are inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss.
- lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked, or itchy nose (rhinitis)

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

In patients with a reduced functioning of the heart the use of this medicine can cause fluid accumulation (swollen ankles, swollen fingers, mild peripheral oedema).

It is better not to use this medicine when you have chicken pox (varicella). Long-term use of any pain medication against headache, may worsen the headache. If you believe this is the case with you, please contact your doctor for advice.

Naproxen may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems getting pregnant. Tell your doctor, who will decide what to do (see section 2 "**Pregnancy and breast-feeding**").

If you are **elderly** you may have an increased risk of side effects. Tell your doctor **immediately** if you suffer with any unusual symptoms of the stomach or bowel.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take Naproxen Tablets.

Children

Naproxen is not recommended for use in children below 5 years of age.

Other medicines and Naproxen Tablets

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

- other pain killers, like aspirin, ibuprofen, diclofenac and paracetamol
- medicines that prevent blood clotting such as warfarin, heparin, ticlopidine or clopidogrel
- A hydantoin (for epilepsy), like phenytoin
- diuretics (water tablets) (for high blood pressure), such as furosemide
- An 'ACE inhibitor' or any other medicines to treat high blood pressure such as propranolol, enalapril, or cilazapril
- An angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan
- a 'cardiac glycoside' used to treat heart problems, such as digoxin
- a steroid used to treat swelling and inflammation, like hydrocortisone, prednisolone and dexamethasone
- probenecid, a medicine to treat gout
- certain medicines used to treat mental illness, such as lithium or 'SSRIs' like fluoxetine or citalopram
- selective serotonin reuptake inhibitors such as Fluoxetine or Citalopram
- medicines used to treat epilepsy, such as phenytoin and hydantoin
- sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and sulfonamide antibiotics used to treat infections
- a sulfonyleurea used to treat diabetes, such as glimepiride or glipizide
- a 'quinolone antibiotic' used to treat infections, such as ciprofloxacin or moxifloxacin
- ciclosporin or tacrolimus, medicines used for skin problems or to prevent transplant rejection after surgery
- methotrexate, a medicine used to treat skin conditions, rheumatoid arthritis and cancer
- colestyramine, a medicine used to reduce cholesterol
- zidovudine, a medicine used to treat AIDS and HIV infections
- mifepristone, a medicine used to end pregnancy or to bring on labour if the baby has died
- Aspirin/ acetylsalicylic acid to prevent blood clots

If any of the above apply to you, or if you are not sure, **talk to your doctor** or pharmacist before you take Naproxen Tablets. Please note that the above medicines may be known to you by other names, often the brand names. In this section only the active ingredient or therapeutic group of the medicine is given, and not the brand name. Always thoroughly check the pack and information leaflet of the medicines you are already using for the active ingredient or therapeutic group of that medicine. It may still be all right for you to take Naproxen tablets and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

Do not take Naproxen Tablets if you are more than 6 months pregnant or if you are breast-feeding (see section 2 "**DO NOT take Naproxen Tablets**"). Your doctor may prescribe Naproxen Tablets for you during early pregnancy if they decide it is suitable.

Naproxen may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Naproxen Tablets may make you tired, drowsy, dizzy, cause blurred vision, difficulty in sleeping or make you feel depressed. Talk to your doctor if any of these happen to you and do not drive or use machines.

Naproxen Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE NAPROXEN TABLETS

Always take Naproxen Tablets exactly as your doctor has told you. Medicines such as Naproxen Tablets may be linked with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with higher doses and long term treatment. Do not take more than the recommended dose or exceed the length of the treatment. Check with your doctor or pharmacist if you are not sure.

Method of administration:

Naproxen Tablets should be swallowed whole with a glass of water, with food. Take your tablets at the same time each day. You should make sure that you have enough to drink (stay well hydrated) when you are taking Naproxen. This is particularly important for people who have problems with their kidneys. While you are taking Naproxen Tablets your doctor will want to see you to check you are on the right dose for you and look for any side effects. This is particularly important if you are elderly.

The recommended doses are:

Adults

Muscle, joint or tendon problems and Period pain

The usual starting dose is 500 mg, followed by one 250 mg tablet every 6 to 8 hours as needed.

Arthritis and ankylosing spondylitis

The usual dose is between 500 mg and 1000 mg.

The dose can be taken all at once, or half the dose may be taken twice a day.

Gout: The usual starting dose is 750 mg, then 8 hours later 500 mg followed by one 250 mg tablet every 8 hours as needed.

Elderly and patients with liver and kidney problems

The doctor will decide the right dose for you, it will usually be lower than for other adults.

Children over 5 years, rheumatoid arthritis
The usual dose is 10 mg per kilogram of body weight each day.
The total daily dose is split into two doses, to be given 12 hours apart.

If you take more Naproxen Tablets than you should
If you take too many Naproxen Tablets, talk to your doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Naproxen Tablets
If you have missed a dose, continue in accordance with your doctor's prescription. Never take a double dose of Naproxen Tablets to make up for a forgotten dose.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Naproxen Tablets can cause side effects, although not everybody gets them.

Serious side effects:
Stop taking Naproxen and tell your doctor straight away if any of the following side effects happen. You may need urgent medical treatment:

- Allergic reactions, signs include:**
Rare (may affect upto 1 in 1,000 people)
● difficulty breathing, tightness in your chest
Not known: frequency cannot be estimated from the available data
● sudden swelling of your throat, face, hands or feet
● skin rashes, blisters or itching

- Serious stomach or gut problems, signs include:**
Uncommon (may affect upto 1 in 100 people)
● bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds
● bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea

- Rare** (may affect upto 1 in 1,000 people)
● ulcers or holes forming in your stomach or gut, seen as upset stomach, stomach pain, fever, feeling or being sick
● problems with your pancreas, seen as severe stomach pain which spreads to your back
Not known: frequency cannot be estimated from the available data
● worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss

- Severe skin rashes, signs include:**
Rare (may affect upto 1 in 1,000 people)
● a severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time
● blistering of skin when exposed to sunlight (porphyria cutanea tarda) seen most on arms, face and hands

- Liver problems, signs include:**
Rare (may affect upto 1 in 1,000 people)
● yellowing of your skin or the whites of your eyes (jaundice)
● feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems, shown in blood tests

- Heart attack, signs include:**
Rare (may affect upto 1 in 1,000 people)
● chest pain which may spread to your neck and shoulders and down your left arm

- Stroke, signs include:**
Rare (may affect upto 1 in 1,000 people)
● muscle weakness and numbness, which may only be on one side of your body
● a sudden altered sense of smell, taste, hearing, vision or confusion

- Meningitis, signs include:**
Rare (may affect upto 1 in 1,000 people)
● fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion. Most likely in people with autoimmune conditions such as 'systemic lupus erythematosus'
● if you notice any of the serious side effects mentioned above, stop taking Naproxen and tell your doctor straight away

- Other possible side effects:**
Common: (may affect upto 1 in 10 people)
● prolonged bleeding time
● heartburn, constipation, abdominal pain, nausea
● headache, dizziness, drowsiness during the day
● light-headedness
● ringing in the ears (tinnitus)
● shortness of breath
● fluid accumulation (oedema)
Uncommon: (may affect upto 1 in 100 people)
● blurred vision
● feeling dizzy
● hearing disorders
● palpitations
● vomiting
● inflammation of the mucous membrane of mouth
● digestive disorder
● diarrhoea
● bruising
● thirst
● indigestion
● purpura
● perspiration
Rare: (may affect upto 1 in 1,000 people)
● blood problems, like anaemia or changes to the numbers of white blood cells
● severe hypersensitivity to certain substances (anaphylactic reaction)
● reduced appetite
● Insomnia
● difficulty sleeping or changes in your patterns of dreaming
● difficulty with your memory
● reduced ability to concentrate
● mild depression

- infectious disease characterized by inflammation of cerebral membrane and/or spinal cord membrane (aseptic meningitis)
- confusion or seeing and possibly hearing things that are not there (hallucinations)
- repeated attacks of transient itching and fluid accumulation (oedema) of the skin and /or mucous membranes (angioneurotic oedema)
- fits or seizures (convulsions)
- eye abnormalities
- elevated blood pressure and insufficient pumping strength of the heart (heart failure)
- blood count abnormalities, inflammation of a blood vessel (vasculitis)
- dyspnea attacks due to cramping of the muscles and swelling of the mucous membrane of the respiratory tract frequently involving coughing and phlegm (asthma)
- pneumonia
- oesophagitis
- haematemesis
- pancreatitis
- feeling of dry mouth
- throat irritation
- increased liver enzyme values
- hair loss
- skin being more sensitive to the sun
- severe skin or mucosal reactions with peeling or blistering (e.g. Stevens-Johnson's syndrome) erythema multiforme, exacerbation of skin diseases (e.g. lichen planus, erythema nodosum)
- muscle weakness
- reduced renal function
- increased urination (pollakisuria)
- blood in your urine or kidney problems
- increased serum creatinine
- increased potassium level in blood tests
- fever
- reduction of body temperature
- fatigue

- Not known:** frequency cannot be estimated from the available data
● allergic reactions
● gastritis
● obstruction of the upper and lower gastrointestinal tract
● 'systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain
● problems for women in getting pregnant
● generally unwell
● muscle pain
● 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
● 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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NAPROXEN TABLETS

Keep out of the reach and sight of children.

Do not use Naproxen Tablets after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last date of that month.

This medicinal product does not require any special storage conditions. Do not use Naproxen Tablets if you notice any visible signs of deterioration. Store in a dry place below 25°C. Protect from light. Keep container tightly closed.

Do not throw away 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 Naproxen Tablets contain
The active substance is naproxen.
The other ingredients are lactose, maize starch, povidone (E 1201), sodium starch glycollate, magnesium stearate (E470b) and quinoline yellow (E104).

What Naproxen Tablets look like and contents of the pack
Naproxen Tablets BP 500 mg are yellow coloured, capsule shaped uncoated tablets with score line between 'NPY' and '500' embossed on one side and plain on the other side.
Naproxen Tablets are available in packs of 28, 30, 56, 60, 84, 100, 250, 500 and 1000 tablets.
(Not all pack sizes may be marketed).

Marketing Authorisation Holder:
Activase Pharmaceuticals Limited
11 Boumpulinas, 3rd Floor,
P.C. 1060, Nicosia, Cyprus

Manufacturer:
Medreich PLC,
Warwick House, Plane Tree Crescent,
Feltham, TW13 7HF

This leaflet was last revised in 10/2025
A0268/O/PIL/A3