

PACKAGE LEAFLET: INFORMATION FOR THE USER

Naproxen 250mg and 500mg Tablets

Naproxen

(Referred to as Naproxen Tablets in this leaflet)



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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
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1. What Naproxen Tablets are and what they are used for

Naproxen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAID). It is a painkiller and antipyretic (reduces fever). Naproxen works by reducing inflammation and relieving pain, swelling and stiffness in the joints and muscles. There are a number of painful conditions that can affect your joints and muscles, which can be helped by taking Naproxen. These conditions include:

- rheumatoid arthritis
- juvenile rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis (arthritis in the spine)
- acute gout
- musculo-skeletal disorders such as sprains, back pains and fibrositis

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 this medicine (listed in section 6)
- if you have taken another non-steroidal anti-inflammatory drug before (including aspirin) and suffered an unpleasant or allergic reaction including asthma, redness and itching of the skin or an itchy, running nose
- if you are taking Mifamurtide (used in anti-tumour treatment)
- if you have or have had a history of recurrent stomach ulcer/bleeding or know that you have suffered with ulcers in the past
- if you have serious problems with your liver, kidney or heart
- if you are in the last three months of pregnancy

Warnings and Precautions

Talk to your doctor or pharmacist before taking Naproxen Tablets:

- if you have any problems with your stomach or bowel
- if you have problems with your liver or kidneys
- if you have haemophilia or problems with your blood not clotting
- if you have heart trouble or high blood pressure
- if you are elderly
- if you have an infection
- if you have asthma or if you suffer from a connective tissue disorder (such as lupus)
- if you have an allergic disorder
- if you have chicken pox or shingles
- if you are taking another non-steroidal anti-inflammatory drug (NSAID).

Tell your doctor if any of the above applies to you.

Medicines such as Naproxen Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment; however, short-term used in those with no cardiovascular risk may also experience a small increased risk in thrombotic events. Do not exceed the recommended dose or duration of treatment.

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.

There is a risk of bleeding or perforation of the stomach and stomach ulcers with the use of Naproxen. This is higher in the elderly, if you have a history of stomach ulcer, or if you smoke. Increased risk with dose of naproxen. If you think that you might be at risk of these conditions, you should speak to your doctor or pharmacist.

Other medicines and Naproxen Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription, or any of the following:

- phenytoin to treat or prevent convulsions, anticoagulants to thin your blood, such as warfarin, heparin, clopidogrel and ticlopidine or some antibiotics such as ciprofloxacin and sulphonamides to treat infection, as the levels of all these medicines in your blood may increase when you start taking Naproxen
- antibacterials, (such as aminoglycosides) concomitant use with Naproxen could decrease the function of your kidneys
- furosemide, amiloride, triamterene or other water tablets, as these may not work as well when you start taking Naproxen
- lithium or moclobemide to treat mental illness, as your body may not be able to clear these as quickly when you start taking Naproxen
- mifamurtide, used in anti-tumour treatment
- methotrexate (for rheumatoid arthritis)
- cardiac glycosides (e.g. digoxin), used to treat heart problems, and other drugs (e.g. disopyramide) used to control heart rhythm
- probenecid, for gout, as the dose of Naproxen you will need will be lower than usual
- certain drugs used to treat diabetes - chlorpropamide, glibenclamide, gliclazide and tolbutamide
- drugs for high blood pressure including ACE inhibitors (e.g. lisinapril), beta-blockers (e.g. propranolol) and angiotensin II antagonists (e.g. losartan)
- ritonavir or zidovudine, used to treat viral infections, can increase the risk of toxicity or damage to the blood.
- oxipentifylline, used for poor circulation
- drugs used to lower cholesterol (e.g. colestyramine)
- corticosteroids (e.g. prednisolone), used to treat allergic conditions and inflammation
- penicillamine, concomitant use with Naproxen can lead to decreased kidney function
- mifepristone (used in abortions)
- ciclosporin and tacrolimus (used after transplant surgery)
- aspirin/acetysalicylic acid to prevent blood clots.

There may be some problems when naproxen is taken with alcohol, including bleeding of the stomach and stomach ulcers.

Naproxen Tablets with food and drink - You should swallow Naproxen Tablets with a glass of water, preferably with or after food.

Pregnancy breast-feeding and fertility

- Do not take Naproxen if you are in the last three months of pregnancy.
- Talk to your doctor before taking Naproxen if you are up to six months pregnant (first and second trimester), think you are pregnant, or plan to get pregnant. Your doctor will decide if you should take Naproxen.
- Talk to your doctor if you are breast-feeding. Small amounts of Naproxen can pass into breast milk. Your doctor will decide if you should take Naproxen.
- 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.

Taking naproxen late in pregnancy can cause delayed or prolonged labour and may cause bleeding problems, kidney problems and problems with the circulation of the blood in newborn babies.

Driving and using machines

Do not drive or operate machinery if you feel drowsy or have blurred vision after taking Naproxen Tablets.

Naproxen Tablets contain lactose and sodium

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

This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially 'sodium – free'.

3. How to take Naproxen Tablets

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

These tablets should be taken as instructed after meals. The dose you should take will depend on what you are taking Naproxen for.

Dosage

Adults: *Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis:* 250mg or 500mg twice a day.

Acute gout: 750mg is taken at once then 250mg every eight hours until the attack has passed.

Musculo-Skeletal Disorders (sprains etc): the usual dose is 500mg followed by 250mg every six to eight hours, up to a maximum 1250 mg (5 x Naproxen 250 mg tablets) per day after the first day.

Elderly: If you are elderly the dose you take will be similar to other adults but should be the lowest dose that is effective.

Children: In children over 5 years with juvenile rheumatoid arthritis 10mg/kg bodyweight per day is usually given, in divided doses.

If you take more Naproxen Tablets than you should

If you take more Naproxen Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Symptoms of overdose include drowsiness, apnoea, heartburn, indigestion, feeling and being sick. Take the container and any remaining tablets with you.

If you forget to take Naproxen Tablets

If you forget to take Naproxen Tablets take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Naproxen Tablets

Do not stop taking Naproxen Tablets without talking to your doctor, even if you feel better. It is important that you take the full course of Naproxen prescribed by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very serious side effects - If any of the following happen, **stop taking Naproxen Tablets and tell your doctor immediately** or go to your nearest hospital emergency department:

- if you have severe stomach pain
- if you pass black, tarry stools
- if you vomit any blood or dark particles that look like coffee grounds
- if you have an allergic reaction causing difficulty in breathing, tightness of the chest, swelling of the face, throat or tongue, sore dry itchy skin, or severe skin rashes
- if you notice sensitivity of the skin to sunlight, red spots or rash on the skin or unusual bruising or bleeding of the skin
- if your skin or the whites of your eyes become yellow
- if you experience headache, neck stiffness, fever, confusion, feeling or being sick (symptoms of a milder-form of meningitis known as aseptic-meningitis),
- if you develop fever, sore throat, fatigue and ulcers or lesions, severe rash that develops quickly with blisters or peeling of your skin and possibly blisters in your mouth, throat, genital area or eyes (symptoms associated with Stephens-Johnson Syndrome or Toxic Epidermal necrolysis (TEN))

Naproxen Tablets can make colitis and Crohn's disease worse.

Occasionally stomach ulcers may develop.

Some anti-inflammatory/pain relieving medicines (particularly at high doses and in long-term treatment) may be associated with a small increased risk of heart attack or stroke.

Other possible side effects:

Rare (occurring in less than 1 in 1,000 patients): high blood pressure, effects on the kidneys or liver, decreased vision due to clouding of the cornea, or papilloedema (intracranial pressure causing optic disc swelling, symptoms include headache.). Blood disorders (which may cause fever, sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, prolonged bleeding, unexplained bleeding or bruising).

Unknown Frequency: a mild form of meningitis (aseptic-meningitis), causing headache, neck stiffness, fever, confusion, feeling or being sick, allergic reaction, skin rashes, itchy/runny nose, hair loss, menstrual disturbances in women, impotence in men, reversible infertility, nervousness, nightmares, insomnia, depression, sleeplessness, lack of concentration, feeling dizzy or confused, loss of memory, feeling or being sick, feeling generally unwell, giddiness, drowsiness, tiredness, blood in the urine, wind, indigestion, heartburn, mouth ulcers, headache, heart condition, cough, weakness, pins and needles or slight swelling of the hands and feet, fluid in the tissues, red or purple discolouration of the skin, yellow skin (jaundice), inflammation of the lungs, inflammation of the blood vessels (vasculitis), upset stomach, stomach or abdominal pain and diarrhoea, flatulence, constipation, stomach ulcers, nausea, vomiting, hallucinating, hearing problems, ringing in the ears and changes in eyesight.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta:

ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

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 sight and reach of children.

Do not use this medicine after the expiry date, which is shown on the label or carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help protect the environment.

6. Contents of the pack and other information

What Naproxen Tablets contain

The active substance is naproxen.

Other ingredients are lactose, maize starch, povidone, sodium starch glycolate, magnesium stearate, yellow lake CLF 3076 which consists of E104 (quinoline yellow aluminium lake) and E172 (iron oxide).

What Naproxen Tablets look like and contents of the pack

The tablets are available in two strengths of 250mg and 500mg.

Naproxen 250mg Tablets are yellow, circular, flat faced tablets marked NXN 250 with a breakline on one face and CP on the reverse.

Naproxen 500mg Tablets are yellow capsule shaped tablets marked NXN 500 with a breakline on one face and CP on the reverse.

Naproxen Tablets are available in blister packs of 28 tablets in cartons.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Naproxen 250mg Tablets	29831/0150
Naproxen 500mg Tablets	29831/0149

This is a service provided by the Royal National Institute of Blind People.

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