

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Naproxen 250mg and 500mg 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse. See section 4.

**What is in this leaflet:**

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

**1. What Naproxen is and what it is used for**

Naproxen is a ‘Non Steroidal Anti Inflammatory Drug’ or NSAID.

Naproxen can lessen inflammation and pain in joints and muscles

- diseases of joints such as rheumatoid arthritis (including in children), osteoarthritis, ankylosing spondylitis. Naproxen cannot cure arthritis but is used to give relief of some symptoms such as inflammation, swelling, stiffness and joint pain

- attacks of gout
- muscle and bone disorders
- painful periods.

**2. What you need to know before you take Naproxen****Do not take Naproxen if you:**

- Are allergic or (hypersensitive) to Naproxen sodium or any of the other ingredients of this medicine (see section 6).
- Have a history of allergy to other NSAIDs (e.g. Aspirin, Diclofenac, Ibuprofen), which includes attacks of asthma (wheezing), swelling of the skin, nose and throat, skin rashes or a runny nose
- Have now or have ever had any problems with your stomach or gut (intestine) like an ulcer or bleeding
- Have a history of gastrointestinal bleeding, two or more episodes of peptic ulcers, stomach bleeding or perforation related to the use of NSAIDs.
- Have severe problems with your kidneys, liver or heart.
- Are in the last three months of pregnancy (last trimester) or if you are breast feeding).

If you are not sure about any of the above conditions, please ask your doctor.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Naproxen tablets:

- 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
- If you use other non-steroidal antiinflammatory medicines (NSAIDs) or any medication which may cause bleeding or ulcers in the stomach
- If you have a history of gastrointestinal disease e.g. ulcerative colitis, Crohn’s disease
- If you smoke
- If you drink alcohol
- Elderly patients have a higher risk of getting side effects, especially from the stomach
- If you have or have had high blood pressure or any liver, kidney or heart problems
- If you have or have had bronchial asthma, other breathing problems or nasal polyps
- If you have systemic lupus erythematosus or other connective tissue disorders
- If you have a blood clotting disorder
- Serious skin reactions including (Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported in association with Naproxen. Stop using Naproxen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- Naproxen tablets may hide the symptoms of an infection
- If you develop visual disturbances while taking Naproxen you should have an eye examination
- Taking a painkiller for headaches too often or for too long can make them worse
- If you are a woman trying to become pregnant or undergoing investigation of infertility.

When taking Naproxen tablets, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

**Children**

Do not give this medicine to children under 5 years old.

**Other medicines and Naproxen**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines obtained without prescription. In particular, tell your doctor or pharmacist if you are taking:

- aspirin/acetylsalicylic acid to prevent blood clots
- other NSAIDs such as COX II inhibitors
- Medicines which thin the blood or which prevent blood clotting (e.g. heparin, warfarin or aspirin)
- A steroid (for swelling and inflammation) like, hydrocortisone, prednisolone and dexamethasone, if needed the doctor will reduce the dose of the steroid slowly and monitor for side effects.
- Corticosteroids (e.g. prednisolone), if needed the doctor will reduce the dose of the steroid slowly and monitor for side effects
- A diuretic (water tablet) (for high blood pressure) like, furosemide
- Medicines to treat high blood pressure (e.g. captopril, ramipril or propranolol, losartan or candesartan)

- Ciclosporin or tacrolimus (for skin problems or after an organ transplant)
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died) – do not take NSAIDs 8-12 days after mifepristone
- Zidovudine (used to treat AIDS and HIV infections)
- A ‘quinolone antibiotic’ (for infections) like, ciprofloxacin or moxifloxacin
- Probenecid (for gout)
- Methotrexate (used to treat skin problems, arthritis or cancer)
- Bisphosphonates (used to treat bone diseases)
- Antacids
- Colestyramine (used to treat high blood cholesterol levels) - take 1 hour before or 4 to 6 hours after cholestyramine to avoid interference with absorption
- Certain medicines for mental health problems like, lithium or ‘SSRIs’ like fluoxetine or citalopram
- A hydantoin (for epilepsy) like, phenytoin
- Sulfonamide medicines like, sulfamethoxazole, hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections)
- A sulfonylurea (for diabetes) like, glibenclamide, glimepiride or glipizide
- A ‘cardiac glycoside’ (for heart problems) like, digoxin

**Naproxen tablets with food, drink and alcohol**

Naproxen should preferably be taken with or after food.

You should refrain from alcohol consumption while taking NSAIDs.

**Pregnancy breast-feeding and fertility:**

- 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 this medicine.
- Do not take naproxen if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby’s tendency to bleed and cause labour to be later or longer than expected. You should not take naproxen 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, naproxen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydrannios) 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.

**Breast-feeding**

If you are breast-feeding, you should not take Naproxen tablets.

**Fertility**

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.

**Tests**

If you need any blood or urine tests tell your doctor you are taking Naproxen tablets. The tablets may need to be stopped 48 hours before a test, as they may interfere with the results.

**Driving and using machines**

Naproxen may make you feel dizzy, drowsy or tired and may cause blurred vision. Make sure you are not affected before you drive or operate machinery.

**Naproxen Tablets contain Lactose and Sunset yellow (E110)**

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sunset yellow may cause allergic reactions.

**Information on sodium content**

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

**3. How to take Naproxen**

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

Swallow the tablets whole with a drink of water, with or after food.

**Dose**

Your doctor should prescribe as low a dose as possible. This will reduce any side effects you may experience.

**Adults****Muscle, bone disorders and period pain**

- The usual starting dose is 500 mg, followed by 250 mg tablet every 6 to 8 hours as needed. Up to a maximum of 1250mg a day may be given after the first day.

**Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis**

- 500mg-1g a day in two doses at twelve hour intervals. If 1g is needed this can be given as two 500mg doses or as a single dose.

**Attack of gout.**

- The usual starting dose is 750 mg, followed by a 250 mg tablet every 8 hours until the attack has passed.

**Elderly or patients with liver or kidney impairment**

Reduced dosage may be given to the elderly, or patients with liver or kidney disease. Naproxen should not be given to patients with a baseline creatinine clearance below 30ml/min.

**Use in children and adolescents Children over 5 years for juvenile rheumatoid arthritis**

10mg per kg of body weight a day, taken in two doses at 12 hour intervals.

**If you take more Naproxen tablets than you should**

It is important not to take too many tablets. Contact your doctor, pharmacist or nearest hospital emergency department immediately if you have taken more tablets than you should.

**Symptoms of overdose** are headache, feeling or being sick, heartburn, diarrhoea, disorientation, bleeding of the stomach or intestines, unconsciousness, drowsiness, dizziness, ringing or buzzing in the ears, fainting, fits and excitation.

**If you forget to take Naproxen**

- If you forget to take your tablets, take your forgotten dose as soon as you remember, unless it is nearly time for your next dose.
- Do not take a double dose to make up for a forgotten dose.
- If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone will get them. If any of the side effects get worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Medicines such as Naproxen may be associated with a small increased risk of heart attack (‘myocardial infarction’) or stroke.

**Stop taking Naproxen tablets and see your doctor or go to your nearest hospital emergency department immediately if you experience any of the following serious side effects (not known, frequency cannot be estimated from the available data):**

- 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); vomit any blood or dark particles that look like coffee grounds; pancreatitis (causing fever, stomach pain, sickness).
- Pass blood in your faeces (stools/motions) or black tarry looking stools (signs of bleeding and perforation of the stomach and intestines).
- Vomit any blood or dark particles that look like coffee grounds
- Have an **allergic reaction:**
- Swelling of the face, mouth, tongue, airways or body
- Skin reactions including: hives (pale/red raised skin with severe itching), blistered skin, 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).
- 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).
- 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).
- Inflammation of the liver (Hepatitis sometimes fatal symptoms include feeling tired, Loss of appetite, feeling or being sick and pale coloured stools)
- **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 necrosis); blistering of skin when exposed to sunlight (pseudoporphyria).
- Difficulty breathing or wheezing, coughing up blood.
- 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
- Heart attack or stroke.

**Common (may affect up to 1 in 10 people)**

- Confusion, headache
- Ringing in the ears (tinnitus)
- Changes in vision (you should go for an eye test if you notice changes in vision)
- Tiredness, drowsiness, dizziness (lightheadedness)
- Rashes

**Uncommon (may affect up to 1 in 100 people)**

- Depression
- Fluttering feeling in your chest (palpitations)
- Abnormal dreams, forgetfulness, difficulty sleeping (insomnia)
- Difficulty concentrating,
- Sensitivity of the skin to light (may cause blistering)

**Rare (may affect up to 1 in 1,000 people)**

- High blood potassium levels (causing irregular, slow heart beat, feeling sick)
- Hair loss
- Jaundice (yellow skin or eyes)
- Hearing difficulties
- Inflammation of blood vessels (causing fever, swelling and general unwellness)
- Anaemia (may cause fainting, chest pain, breathlessness)
- Accumulation of eosinophils (type of white blood cells) in the lungs (eosinophilic pneumonitis may cause cough, fever, difficulty in breathing and sweating at night)
- Worsening of asthma
- Muscle weakness/pain
- Skin rash or blistering, or your skin becoming more sensitive on exposure to sunlight (pseudoporphyria)

**Very rare (may affect up to 1 in 10,000 people)**

- Changes in the numbers and types of blood cells (if you develop sore throats, nose bleeds or infections consult your doctor)
- Fits or seizures, aseptic meningitis (may cause fever, feeling or being sick, disorientation, headache, neck stiffness and sensitivity to light)
- Blisters or sores on the skin
- Kidney damage or infection (may cause blood in the urine, decrease in amount of urine passed, feeling or being sick)
- Inflammation of the pancreas; pancreatitis (causing fever, stomach pain, sickness).
- Medicines such as naproxen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

**Not Known (frequency cannot be estimated from the available data)**

- Low amounts of white cells in the blood (may cause fever or frequent infections)

- Runny nose
- Lowered female fertility
- Seeing, hearing or believing things which are not real (hallucinations).
- High blood creatinine levels seen in blood tests
- Kidney failure
- Kidney disease (may cause changes in the need to or amount of urine)
- Thirst, fever
- Inflammation in the eye (causing eye pain or changes in vision)
- Tingling or “pins and needles” or numbness of your hands
- A spinning sensation (vertigo)
- Abnormal liver function seen in tests
- Worsening of Parkinson’s disease
- General feeling of discomfort and illness
- Swelling in the eye (causing headaches or blurred vision).
- Wind, constipation, water retention (may cause swelling in the limbs)
- High blood pressure and heart failure
- Less number of blood cells produce by body (Aplastic anaemia- if you develop fever, fatigue or infection consult your doctor)
- Difficulty in breathing (Dyspnoea)
- Tightening of the muscles that line the airways (bronchi) in your lungs (bronchospasm- may cause pain, tightness, and a feeling of constriction in the chest and back)
- Ulcers on the inner cheeks, gums and tongue (ulcerative stomatitis)
- Swelling of hands, feet or legs (oedema)
- Flatulence
- Abdominal discomfort or pain
- Problems with the way your heart pumps blood around the body or damage to blood vessels (signs include chest pain, tiredness, shortness of breath, feeling faint, general pain)
- Problems for women in getting pregnant
- Pneumonia or swelling your lungs
- Heartburn, nausea, vomiting, constipation, diarrhoea, indigestion
- Sore mouth or mouth ulcers
- Sweating

**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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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.

#### 5. How to store Naproxen

- Keep this medicine out of the sight and reach of children.
- Store in a cool dry place. Protect from light. Do not store above 25°C.

- Do not use this medicine after the expiry date which is printed on the pack. The expiry date refers to the last day of that month.
- 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 contains**

- The active substance is naproxen. Each tablet contains either 250 mg (milligrams) or 500 mg of naproxen
- The other ingredients are sodium lauryl sulfate, lactose, maize starch, crospovidone, magnesium stearate and the colours quinoline yellow (E104) and sunset yellow (E110)

**What Naproxen looks like and contents of the pack**

Naproxen 250 mg tablets: Pale yellow, flat bevelled edge tablets with N breakline 250 on one side and BL on the other.

Naproxen 500 mg tablets: Pale yellow, oblong tablets with N breakline 500 on one side and BL on the other.

Naproxen 250 mg tablets are supplied in containers of 28, 56, 250 tablets and blisters of 28, 56, 84 and 112 tablets.

Naproxen 500 mg tablets are supplied in containers of 28, 56, 100, 500 tablets and blisters of 28, 56, 84 and 112 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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**Naproxen 250mg Tablets; PL 17907/0339**

**Naproxen 500mg Tablets; PL 17907/0340**

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