

Patient information leaflet

NAPROXEN TABLETS 250MG & 500MG

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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 Tablets
4. Possible side effects
5. How to store Naproxen Tablets
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1. What Naproxen is and what it is used for

- Naproxen belongs to the group of drugs termed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
- Naproxen is used to help to relieve pain and joint inflammation.
- Naproxen can be used to treat rheumatoid arthritis, osteoarthritis, ankylosing spondylitis (causing pain and stiffness in the back), back pain, neck pain, swollen or painful tendons and dysmenorrhoea (painful menstrual period).
- It also used to treat acute gout, sprain or strained muscles.
- Also used to treat rheumatoid arthritis in children over five years of age.

2. What you need to know before you take Naproxen**DO NOT TAKE these tablets if you:**

- are allergic to Naproxen or any other ingredient of this tablet (these are listed in Section 6)
- have or have had stomach ulcer, perforation or bleeding of the stomach and intestine
- have had wheeziness (asthma), hay fever, itchiness or skin rash (urticaria) after taking aspirin or other non-steroidal anti-inflammatory drugs
- have or ever had peptic ulceration (ulcer in your stomach or duodenum) or bleeding in your digestive tract
- have severe problem with your liver, kidney (not receiving dialysis) or heart
- are in last three months of pregnancy.
- have a bleeding disorder such as cerebro-vascular bleeding
- pass blood in your faeces (stools/motion)
- pass black tarry stools, vomit any blood or dark particles that look like coffee grounds
- suffering from haemorrhoids (“piles”) or are at an increased risk of rectal bleeding

Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you:

- have ever suffered any allergic reaction after taking aspirin or other NSAIDs
- are suffering from or have a history of asthma, hay fever or allergies like swelling of the tongue or larynx (angioedema), inflammation of the nose (rhinitis), or nasal polyps, breathing difficulties (bronchospasm)
- have an autoimmune condition, such as ‘systemic lupus erythematosus’ (SLE, causes joint pain, skin rashes and fever) and colitis or Crohn’s disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss)
- are suffering from any blood clotting disorders or are taking anticoagulant therapy (blood thinning medicines) e.g. heparin or warfarin
- have heart problems such as swollen feet or hands
- are having liver or adrenal function tests
- have kidney or liver problems, including alcohol related disease or other forms of cirrhosis of the liver

Medicines such as Naproxen 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. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you may 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.

Other medicines and Naproxen Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking:

- other painkillers such as aspirin, ibuprofen, diclofenac and paracetamol or COX II inhibitors
- medicines for epilepsy (eg. phenytoin)
- medicines for blood clots (eg. warfarin)
- medicines for infections (sulphonamides like hydrochlorothiazide)
- medicines for heart failure (diuretics such as furosemide or cardiac glycosides such as digoxin)
- medicines for high blood pressure (propranolol and other beta-blockers, ACE inhibitors e.g. cilazapril)
- angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan
- quinolone antibiotics (for infections), like ciprofloxacin or moxifloxacin
- medicines for gout (probenecid) and psoriasis (methotrexate)
- medicines for arthritis (steroids), prednisolone
- certain medicines for mental health problems like lithium or ‘SSRIs’ like fluoxetine or citalopram
- antacids (medicines to treat indigestion)
- cholestyramine (medicines used to lower cholesterol in blood)
- sulphonylureas (oral anti-diabetic drugs) like glimepiride or glipizide
- zidovudine (used to treat AIDS and HIV infections)
- bisphosphonates (e.g. alendronic acid)(used to treat osteoporosis or other bone diseases)
- tacrolimus and ciclosporin (immunosuppressant medicines usually used to prevent tissue rejection after transplant)
- mifepristone (a medicine prescribed in hospital to terminate pregnancy. You should not take naproxen tablets for 8 to 12 days after being given mifepristone.

Fertility, pregnancy and breast-feeding

Naproxen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. If you are pregnant, ask your doctor or pharmacist before you use any medication. During the first six months of pregnancy, you should only use Naproxen Tablets if your doctor says it is necessary. During the last three months of the pregnancy **you must not** take Naproxen Tablets, as it may harm you and the unborn child and it may cause delayed or prolonged labour. If you are breast-feeding, you should not take these tablets.

Driving and Using Machines

Naproxen may make you feel dizzy, drowsy or tired and may cause problems with your eyesight and balance. You may also feel depressed or have difficulty sleeping. Make sure you are not affected before you drive or operate machinery.

Naproxen Tablet contains lactose

Naproxen Tablets contain lactose monohydrate (milk sugar); If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tests

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

3. How to take Naproxen Tablets

Always take Naproxen Tablets exactly as your doctor has told you. The pharmacist's label should tell you how much to take and how often. Check with your doctor or pharmacist if you are not sure. Your doctor may increase or decrease your doses depending of the severity of your symptoms. To reduce risk of side effects, you will be prescribed the lowest effective dose for the shortest time necessary to control your symptoms. The dosage will depend on the type of pain you have. Swallow the tablets with water, with or after food.

Adult

For rheumatoid arthritis, osteoarthritis and ankylosing spondylitis: The usual dose is 500mg to 1000mg per day taken in two doses 12 hours apart.

For acute gout: The usual starting dose is 750mg immediately followed by 250mg every 8 hours until the attack has passed.

For acute musculoskeletal disorders and dysmenorrhoea: Initially 500mg followed by 250mg at 6-8 hours intervals as needed. The dose should not exceed 1250mg in the first 24-hour period.

Elderly and people with liver and kidney problems

If you are elderly particularly if suffering from kidney problems, you are at a greater risk of experiencing side effects with this medicine. To reduce this risk your doctor will start your treatment with the lowest possible dose to control your symptoms.

Children

Not recommended for children under 16 years of age except for juvenile rheumatoid arthritis in children over 5 years of age: the usual dose is 10mg/10kg/day taken in 2 doses at 12-hour intervals.

If you take more tablets than you should

If you or someone else has swallowed too many tablets, contact your nearest hospital casualty department or doctor for immediate advice

If you forget to take a dose

If you forget to take a dose at the right time take it as soon as you remember. Do not take two doses together. If it is almost time to take the next dose, do not take the missed dose and take the next scheduled dose at the correct time.

4. Possible side effects

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

If you experience any of the following serious side effects **STOP TAKING** this medicine and contact your doctor or pharmacist **immediately**

- **Severe allergic reactions:** Swelling of the face, mouth and throat (angioedema), skin rash, tightness of the chest and difficulty breathing.
- **Serious skin reactions:** Severe skin rash including blistering and peeling of the skin and mucous membranes, including mouth lips and genital region (Stevens Johnson Syndrome), more extensive blistering and peeling of the skin (Toxic Epidermal Necrolysis), blistering of the skin, especially of the hands and feet, when exposed to sunlight (pseudoporphyria)
- **Serious stomach or gut problems:** Passing blood in your faeces (stools/motions) or black tarry looking stools, vomiting blood or dark particles that look like coffee grounds. Ulcers in your stomach or gut (usually causing pain in the abdomen). Ulcers are very serious in elderly patients and may be fatal. Pancreatitis (inflammation of the pancreas causing severe stomach pain which spreads to your back). Worsening of ulcerative colitis or Crohn's disease, usually seen as pain in the abdomen, diarrhoea, vomiting and weight loss.
- **Liver problems:** Seen as yellowing of your skin or the whites of your eyes (jaundice). Feeling tired, loss of appetite and pale coloured stools (hepatitis) and problems in blood tests.
- **Heart attack:** Chest pain, which may spread down the arms, shortness of breath, feeling lightheaded or dizzy and sweating.
- **Meningitis:** A severe headache, stiff neck, vomiting and fever. There may be an increased risk of aseptic meningitis in patients with pre-existing systemic lupus erythematosus (SLE) and other autoimmune diseases.

Other possible side effects:

- **Stomach and gut:** Heartburn, indigestion, inflammation of the lining of the stomach, dry mouth, constipation, wind, inflammation of the food pipe.

- **Blood:** Decrease in the number of blood cells, high levels of potassium in the blood (hyperkalaemia).
- **Mental illness:** Having difficulty sleeping, confusion or seeing and possibly hearing things that are not there (hallucinations).
- **Nervous system:** Fits or seizures, feeling dizzy, pins and needles, difficulty with your memory or concentration, nervousness, euphoria, low body temperature, worsening of Parkinson's disease.
- **Eyes and ears:** Changes to your eyesight, eye pain, ringing in the ears (tinnitus) and hearing loss, dizziness.
- **Heart and circulation:** Oedema, tiredness, shortness of breath (cardiac failure), a fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure, feeling faint, pain, inflammation of blood vessels (vasculitis).
- **Skin:** Itchiness (urticaria), black marks or spots on the skin, tender bruise-like swellings (erythema nosodum), swelling of the neck and face (angioedema), redness of the skin (erythema multiforme), pus containing spots, peeling skin (epidermal necrolysis), sweating.
- **Hair:** Loss of hair (alopecia).
- **Urinary:** Blood and protein in your urine, kidney problems, abnormally frequent urination.
- **Other:** Thirst, fever, feeling tired, muscle pain or weakness, mouth ulcers, stuffy nose (rhinitis), problems for women in getting pregnant.
- **Autoimmune conditions:** development of systemic lupus erythematosus (SLE). Usual symptoms include joint pain, tiredness skin rash and fever.

Medicines such as Naproxen have been associated with a small increased risk of **heart attack** (myocardial infarction) or **stroke**.

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 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 all medicines out of the sight and reach of children.

- Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.
 - Store below 25°C protected from moisture and light.
- 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** 250mg or 500mg of Naproxen
- **The other ingredients are** polyvinyl pyrrolidone, lactose, maize starch, magnesium stearate, sodium starch glycolate, quinoline yellow (E104) and sunset yellow (E110).

See end of **section 2** for further information on **lactose**.

What Naproxen tablets look like and contents of the pack

- **Naproxen 250mg** tablets are yellow, flat, circular tablet with bevelled edge, embossed 'N250' on one face and 'PV' on the other face.
- **Naproxen 500mg** tablets are yellow, oval-shaped tablets with the markings 'N500' on one face and 'PV' on the other face.
- **Pack sizes are** Naproxen tablets 250mg & 500mg are available in the packs of "28, 30, 56, 60, 100, 250 and 500" tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacture:

Pharmvit Ltd, 177 Bilton Road, Perivale,
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