

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), worsening of asthma, muscle weakness/pain, ulcers on the inner cheeks, gums and tongue, hepatitis - sometimes fatal (symptoms include feeling tired, loss of appetite, feeling or being sick and pale coloured stools).

Very rare (may affect 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), anaemia (may cause fainting, chest pain, breathlessness), fits, aseptic meningitis (may cause fever, feeling or being sick, disorientation, headache, neck stiffness and sensitivity to light), severe skin rash with flushing, blisters or ulcers (Stevens-Johnson syndrome), 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 (see section 2), sensing things that are not there, 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", a spinning sensation, abnormal liver function seen in tests, worsening of Parkinson's disease, general feeling of discomfort and illness, swelling of the hands and feet, 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.

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.

How to store

Keep this medicine out of the sight and reach of children.
Store below 25°C in a dry place. Protect from light.

Do not use this medicine after the expiry date which is stated on the carton. 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.

Contents of the pack and other information

What Naproxen tablets contain

- The active substance (the ingredient that makes the medicine work) is naproxen. Each tablet contains either 250mg or 500mg of the active substance.
- The other ingredients are lactose, magnesium stearate, maize starch, polyvidone, E172, E463.

What Naproxen tablets look like and contents of the pack

Naproxen tablets are yellow, uncoated tablets.

Pack size is 28 or 56.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in August 2018

Naproxen 250mg and 500mg tablets

Read 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 Content of the pack and other information

1 What Naproxen tablets are and what they are used for

Naproxen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in joints and muscles. Naproxen tablets are used to treat:

- 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 tablets

Do not take Naproxen tablets if you:

- are in the **last three months of pregnancy** or if you are **breast-feeding**
 - are **allergic to naproxen** or to any of the other ingredients of this medicine (listed in section 6)
 - are **allergic to aspirin or other non-steroidal anti-inflammatory medicines** (NSAIDs), or you have developed signs of asthma (wheezing), runny nose, swelling of the skin or rash when taking these medicines
 - have or have had **stomach or duodenum (gut) ulcers, bleeding in the stomach or intestines** (gastrointestinal bleeding) or have had **two or more** episodes of peptic ulcers, stomach bleeding or perforation
 - have severe **liver, kidney or heart failure**.
- If you are not sure about any of the above conditions, please ask your doctor.

Warnings and precautions

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

- use other **non-steroidal anti-inflammatory medicines** (NSAIDs) or any medication which may cause bleeding or ulcers in the stomach
- have a **history of gastrointestinal disease** e.g. ulcerative colitis, Crohn's disease
- **smoke**
- drink **alcohol**
- are **elderly**
- have or have had **high blood pressure** or any **liver, kidney or heart** problems
- have or have had **bronchial asthma, other breathing problems or nasal polyps**
- have **systemic lupus erythematosus** or other **connective tissue disorders**
- have a **blood clotting disorder**
- are a women trying to **become pregnant** or undergoing investigation of **infertility**.

Other warnings

- 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 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 are elderly or frail, you have a higher risk of getting side effects**, especially from the stomach. If you experience any unusual symptoms from the stomach you must tell your doctor about it.
- Taking a **painkiller for headaches** too often or for too long can make them worse.
- Naproxen tablets may **hide the symptoms of an infection**.
- 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.

Children

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

Other medicines and Naproxen tablets.

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

- 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 or warfarin)
- corticosteroids (e.g. prednisolone), if needed the doctor will reduce the dose of the steroid slowly and monitor for side effects
- diuretics ("water tablets") (e.g. furosemide)
- medicines to treat high blood pressure (e.g. captopril, ramipril or propranolol, losartan or candesartan)
- ciclosporin or tacrolimus
- mifepristone – do not take NSAIDs 8-12 days after mifepristone
- SSRI antidepressants

- zidovudine
- quinolones (e.g. ciprofloxacin)
- probenecid
- methotrexate
- bisphosphonates
- colestyramine (take naproxen 1 hour before or 4 to 6 hours after colestyramine to avoid interference with absorption)
- lithium
- hydantoins (e.g. phenytoin)
- sulphonamides (e.g. sulphamethoxazole)
- sulphonylureas (e.g. glibenclamide or glidazide)
- cardiac glycosides (e.g. digoxin).

Naproxen tablets with food and alcohol

Naproxen tablets 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, are planning to have a baby or if you have problems becoming pregnant ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You **should not** take Naproxen in the first 6 months of pregnancy and **must not** take Naproxen in the last 3 months of pregnancy or during labour.

Breast-feeding

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

Fertility

Naproxen may make it more difficult to become pregnant.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

3 How to take Naproxen tablets

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 **with or after food**.

Recommended dose is:

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

Adults

• 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

Initially 750mg as a single dose then 250mg every 8 hours until the attack has passed.

• Muscle, bone disorders and painful periods

Initially 500mg as a single dose then 250mg every 6-8 hours as necessary. Up to a maximum of 1250mg a day may be given after the first day.

Elderly

Dosage may be reduced in the elderly.

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 twelve hourly 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 casualty 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 tablets

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 one you have missed.

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. 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.

Stop taking Naproxen tablets and contact your doctor immediately if you

- have indigestion, heartburn, pains in your stomach or other abnormal stomach symptoms, feeling or being sick, diarrhoea, worsening of colitis and Crohn's disease (you may have an ulcer or inflammation in the stomach or gut)
- 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, a severe rash with reddening, peeling and swelling of the skin that resembles burns, bumpy, rashes, blisters, dermatitis (skin shedding, itching, swelling)
 - difficulty breathing or wheezing, coughing up blood.

Tell your doctor if you notice any of the following side effects

Common (may affect up to 1 in 10 people) confusion, headache, ringing in the ears, changes in vision (you should go for an eye test if you notice changes in vision), tiredness, drowsiness, dizziness, rashes.

Uncommon (may affect up to 1 in 100 people) depression, irregular heartbeat (palpitations), abnormal dreams, forgetfulness, difficulty concentrating, sensitivity of the skin to light (may cause blistering), difficulty sleeping.