

Naproxen 250mg, 375mg and 500mg Gastro-resistant tablets

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.
- The full name of this medicine is Naproxen 250mg, 375mg and 500mg Gastro-resistant Tablets, but within this leaflet it will be referred to as Naproxen GR tablets.

What is in this leaflet

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1 What Naproxen GR 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 GR tablets are used to treat:

- diseases of joints such as **rheumatoid arthritis (including in children), osteoarthritis and ankylosing spondylitis**. Naproxen GR tablets cannot cure arthritis but are 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 GR tablets **Do not take Naproxen GR tablets if you:**

- are **allergic to naproxen** or to any of the other ingredients of this medicine (listed in section 6)
- have or have had **stomach or duodenum (gut) ulcers, bleeding in the stomach or intestines** (gastrointestinal bleeding)
- have or have had **two or more** episodes of peptic ulcers, stomach bleeding or perforation while taking NSAIDs
- 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 severe **liver, kidney or heart failure**
- are in the **last three months of pregnancy**.

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 GR 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 anti-inflammatory 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**
- Naproxen can cause **serious skin reactions**, some fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrosis
- 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**.

Children

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

Other medicines and Naproxen GR 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. Especially:

- aspirin/acetysalicylic 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, 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
- antacids
- bisphosphonates
- colestyramine (take naproxen 1 hour before or 4 to 6 hours after colestyramine to avoid interference with absorption)

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- lithium
- hydantoins
- sulfonamides
- sulfonylureas (e.g. glibenclamide or gliclazide)
- cardiac glycosides.

Naproxen GR tablets with food

Naproxen GR tablets should preferably be taken with or after food.

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

Breast-feeding

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

Fertility

Naproxen may make it more difficult to become pregnant.

Driving and using machines

Naproxen GR tablets 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 GR 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.

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

This medicine contains potassium, less than 1 mmol (39 mg) per gastro-resistant tablet, i.e. essentially 'potassium-free'.

Tests

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

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E How to take Naproxen GR 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 **whole with or after food** with water, **do not crush or break** them.

Recommended dose:

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 12 hour intervals 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 and 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 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 GR 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.

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If you forget to take Naproxen GR 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 a forgotten dose.

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 GR 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):

- **An allergic reaction:** swelling of the face, mouth, tongue, airways or body; difficulty breathing or wheezing, coughing up blood; skin reactions including; hives (pale/red raised skin with severe itching), 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).
- **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).
- **Heart attack or stroke.**
- **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).
- 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).

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Other side effects:

Stomach or gut problems (not known, frequency cannot be estimated from the available data):

- Heartburn; nausea, vomiting, constipation; diarrhoea; flatulence; indigestion; abdominal discomfort or pain.

Blood disorders (not known, frequency cannot be estimated from the available data):

- Changes to the number and types of blood cells causing illness such as anaemia or an increased risk of infections.

Mental illness (not known, frequency cannot be estimated from the available data):

- Difficulty sleeping (insomnia); abnormal dreams; depression; confusion; seeing, hearing or believing things which are not real (hallucinations).

Nervous system (not known, frequency cannot be estimated from the available data):

- Fits or seizures; dizziness; headache; lightheadedness; drowsiness; pins and needles or numbness of your hands and feet; difficulty concentrating or forgetfulness.

Eyes and ears (not known, frequency cannot be estimated from the available data):

- Changes to your eyesight; eye pain; changes to your hearing including ringing in your ears (tinnitus) or loss of hearing; spinning sensation (vertigo).

Heart and circulation (not known, frequency cannot be estimated from the available data):

- Swelling of hands, feet or legs (oedema); fluttering feeling in your chest (palpitations); high blood pressure; 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).

Chest (not known, frequency cannot be estimated from the available data):

- Difficulty breathing, wheezing or coughing; pneumonia or swelling of your lungs.

Urinary (not known, frequency cannot be estimated from the available data):

- Blood in your urine; kidney problems.

General (not known, frequency cannot be estimated from the available data):

- Thirst; fever; feeling generally tired or unwell; sore mouth or mouth ulcers; muscle pain or weakness; problems for women in getting pregnant; sweating; hair loss.

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 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 GR tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

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

6 Contents of the pack and other information

What Naproxen GR tablets contain

- The active substance (the ingredient that makes the medicine work) is naproxen. Each gastro-resistant tablet contains either 250mg, 375mg or 500mg of the active substance.
- The other ingredients are: methacrylic acid-ethylacrylate copolymer (1:1), lactose, magnesium stearate, maize starch, crospovidone, propylene glycol, sodium hydroxide, triethyl citrate, titanium dioxide (E171), potassium sorbate (E202), sodium citrate (E331), xanthan gum (E415), hydroxypropyl cellulose (E463), purified talc (E553), beeswax.

What Naproxen GR tablets look like and contents of the pack

Naproxen 250mg gastro-resistant tablets are white, round, biconvex, gastro-resistant tablets.

Naproxen 375mg gastro-resistant tablets are white, oval, biconvex, shallow concave gastro-resistant tablets.

Naproxen 500mg gastro-resistant tablets are white, oval, biconvex, deep concave, gastro-resistant tablets.

Pack sizes: 56 tablets

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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