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

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

- 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. 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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 in Naproxen GR tablets (see 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 duodenal (gut) ulcers, bleeding in the stomach or intestines (gastrointestinal bleeding) or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
  - are in the last three months of pregnancy or if you are breastfeeding
  - have severe liver, kidney or heart failure.

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

**Check with your doctor before taking Naproxen GR tablets if you:**

- are on a low potassium diet, as this product contains potassium sorbate. High blood levels of potassium can cause stomach upset and diarrhoea
- 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

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**Naproxen Tablets**

- **250, 375 and 500mg 56's (UK)**

**Approved for print/date**

- Item number: BBBA3033
- OrIGINATOR: RWrey
- ORIGINATION: 24/09/18
- REVISION: 296x210
- Min Body Text Size: 9pt
- Supplier: Actavis UK

**Technical Approval**

- Date sent: N/A
- Date received: N/A

**Colours**

1. Black
2. 3. 4. 5. 6.

**Non Printing Colours**

1. Profile
2. 3.

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**FMD info**

- NA (not a carton)
- Details

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**Report of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- Rare (affects 1 to 10 users in 10,000) 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 (affects less than 1 user in 10,000) changes in the numbers and types of blood cells (if you develop sore throat, 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).

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**Further information**

- **What Naproxen GR tablets contain**
  - The active substance (the ingredient that makes the medicine work) is 250mg, 375mg or 500mg of naproxen.
  - The other ingredients are methacrylic acid-ethylacrylate copolymer (1:1), lactose, magnesium stearate, maize starch, crospovidone, propylene glycol, shellac glaze, sodium hydroxide, triethyl citrate, titanium dioxide (E71), iron oxide black (E172), potassium sorbate (E202), sodium citrate (E331), xanthan gum (E415), hydroxypropyl cellulose (E463), purified talc (E553), beeswax.

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**What Naproxen GR tablets look like and contents of the pack**

250mg tablets are white, round, biconvex, enteric-coated tablets.

375mg and 500mg tablets are white, oval, biconvex, enteric-coated tablets.

Pack sizes: 56 tablets

**Marketing Authorisation Holder and Manufacturer**

Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in August 2018.
Naproxen 250mg, 375mg & 500mg PIL - UK

Item number: BBBA3033
Dimensions: 296x210
Min Body Text Size: 9pt
Supplier: Actavis UK

Adults
- Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
  500mg-1g a day in two doses at twelve hourly intervals. If 1g a day 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 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.

Children over 5 years for juvenile rheumatoid arthritis
10mg per kg of body weight a day, taken in two doses at twelve hourly intervals.

Elderly with kidney disease
Dosage may be reduced in the elderly.

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 casualty department immediately if you have taken more tablets than you should.

Symptoms of an 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 excitement.

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 one you have missed.

Possible side effects
Like all medicines, Naproxen GR tablets can cause side-effects, although not everybody gets them. If any of the side effects get worse, or if you notice any 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 (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 (palae/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
The most commonly observed adverse events are gastrointestinal in nature. Feeling sick, being sick, diarrhoea, wind, constipation and worsening of colitis and Crohn's disease have been reported following administration.

Water retention (may cause swelling in the limbs), high blood pressure and heart failure have been reported in association with NSAID therapy.

Common (affects 1 to 10 users in 100)
- 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 (affects 1 to 10 users in 1,000)
- depression, irregular heartbeat (palpitations), abnormal dreams, forgetfulness, difficulty concentrating, sensitivity of the skin to light (may cause blistering), difficulty sleeping.

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