**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, tell your doctor or pharmacist.

**Before you take Naproxen GR tablets**
- **Do not take Naproxen GR tablets if you:**
  - are allergic to naproxen or 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 had gastroduodenal (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 breast feeding.
  - 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.
- have high blood levels of potassium which 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 GR Tablets 250mg, 375mg & 500mg PIL - UK**

- **Item no:** AAAG6625
- **Print proof no:** 3
- **Origination date:** 13.03.14
- **Originated by:** S.Anson
- **Revision date:** 26.03.14
- **Revised by:** S.Anson
- **Supplier:** Actavis UK

**Approved for print/date**

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**Naproxen 250mg, 375mg & 500mg PIL - UK**

- **Dimensions:** 296 x 210 Reel Fed
- **Pharmacode:** 396 x 210
- **Technical Approval**
- **Min pt size:** 9
- **Supplier:** Actavis UK

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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.
• 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 of the stomach. If you experience any unusual symptoms from the stomach you must tell your doctor about it.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription. Especially:
• other NSAIDs such as aspirin or COX II inhibitors
• corticosteroids (e.g. prednisolone), if needed the doctor will reduce the dose of the steroid slowly and monitor for side effects.
• diuretics (‘water tablets’) such as furosemide
• medicines to treat high blood pressure (e.g. captopril, ramipril or propranolol, losartan or candesartan)
• ciclosporin or tacrolimus
• medicines which thin the blood or which prevent blood clotting (e.g. heparin or warfarin)

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. You should not take Naproxen GR in the first 6 months of pregnancy and must not take Naproxen GR in the last 3 months of pregnancy or during labour. If you are breast-feeding, you should not take Naproxen GR tablets.

Driving and using machines
Naproxen GR tablets may cause dizziness, drowsiness or affect your vision. Make sure you are not affected before you drive or operate machinery.

Sugar intolerance
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.

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.

How to take Naproxen GR tablets
Always take Naproxen GR tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.
Swallow whole with or after food with water, do not crush or break them.

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 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 excitation.

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 (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
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.

Naproxen 250mg, 375mg & 500mg PIL - UK

-colours/plates:
1. Black
2. 
3. 
4. 
5. 
6. Non Printing Colours

Item no: AAAG6625
print proof no: 3
origination date: 13.03.14
originated by: S.Anson
revision date: 26.03.14
revised by: S.Anson
supplier: Actavis UK

Technical Approval
date sent: n/a
technically app: date

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Naproxen GR Tablets
250,375 & 500mg x 56s (UK)

IDE No: 50778110
Dimensions: 296 x 210 (Reel Fed)
Component: Leaflet for Blisters
Pharmacode: 14336

Date Sent: 04/03/14
Technologist: R.Wrey

Actavis BST - Packing Technical
BSTCutterGuideReq@actavis.com

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Approved for print/date

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Actavis BST - Packing Technical
BSTCutterGuideReq@actavis.com