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.

**How to store**

Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package.

Do not use Naproxen GR tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**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 (E172), iron oxide black (E172), 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**

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

Accord, Barnstable, EX32 8NS, UK

This leaflet was last revised in July 2019.

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**Naproxen All strengths Gastro-resistant tablet PIL - UK**

**Item number:** BBBA5454

**Orignator:** G. Worth

**Orignation Date:** 12/07/2019

**Revision Date:** 29/07/2019

**Supplier:** Accord Barnstable

**Dimensions:** 296x210

**Min Body Text Size:** 9pt

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* Please note that only Artwork Studio is permitted to make changes to the above artwork.

No changes are permitted by any 3rd party other than added notes and mark ups for required changes.

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

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

1. Keep this leaflet. You may need to read it again.

   - If you have any further questions, ask your doctor or pharmacist.

2. 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.

3. 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.

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**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 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
- 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. 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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**What Naproxen GR tablets contain and what they are used for**

1. 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.

2. Naproxen GR tablets are used to:

   - 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 of the symptoms such as inflammation, swelling, stiffness and joint pain.
   - attacks of gout
   - muscle and bone disorders
   - painful periods.

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**How to take Naproxen GR tablets**

1. Naproxen tablets can be taken with or without food.

2. The tablets must be swallowed whole with a little water.

3. The tablets may be swallowed immediately after a meal, but this may reduce stomach upset and diarrhoea.

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**Further information**

**How to store**

Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package.

Do not use Naproxen GR tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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**Marketing Authorisation Holder and Manufacturer**

Accord, Barnstable, EX32 8NS, UK

This leaflet was last revised in July 2019.

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**Reporting 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.
Naproxen All strengths Gastro-resistant tablet PIL - UK

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**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.

**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 a painkiller for headaches too often or for too long can make them worse.
- Naproxen GR tablets may hide the symptoms of an infection.

**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
- aspirin/acylsalicylic acid to prevent blood clots
- 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’) such as 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
- SSRIs antidepressants
- zidovudine
- quinolones (e.g. ciprofloxacin)

**Dose**

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

**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.

**Symptoms of an overdose**

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.

**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.

**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, rash.

**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 blisters), difficulty sleeping.