

NAPROXEN 250 mg GASTRO-RESISTANT TABLETS

Package leaflet: Information for the user

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 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.

Important safety information about this medicine:

- **DO NOT TAKE** if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- **STOP TAKING** the medicine and seek immediate medical help if you suffer from any of the following at any time during your treatment:
 - Pass blood in your faeces (stools/motions)
 - Pass black tarry stools
 - Vomit any blood or dark particles that look like coffee grounds.
- **STOP TAKING** the medicine and tell your doctor if you experience indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- Your doctor should prescribe the lowest dose which is effective for you for the shortest period necessary. This will help to reduce the possibility of any side effects. Do not exceed the prescribed dose or duration of treatment.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

What is in this leaflet:

1. What Naproxen Gastro-resistant Tablets are and what they are used for
2. What you need to know before you take Naproxen Gastro-resistant Tablets
3. How to take Naproxen Gastro-resistant Tablets
4. Possible side effects
5. How to store Naproxen Gastro-resistant Tablets
6. Contents of the pack and other information

1 What Naproxen Gastro-resistant Tablets are and what they are used for

Naproxen is a non-steroidal anti-inflammatory drug (NSAID).

Naproxen gastro-resistant tablets are used:

- to treat rheumatoid arthritis, osteoarthritis (degenerative arthritis), ankylosing spondylitis (inflammation affecting joints between the spine and pelvis), juvenile rheumatoid arthritis, acute gout, injury and short term problems with the joints such as sprains and strains
- to relieve stiffness and pain in the back
- to relieve period pains.

2 What you need to know before you take Naproxen Gastro-resistant Tablets

DO NOT take Naproxen if you:

- are allergic (hypersensitive) to naproxen or any of the other ingredients of this medicine (listed in section 6)
- are allergic (hypersensitive) to any other NSAID drugs, e.g. aspirin, ibuprofen
- have had problems in the past caused by taking any NSAIDs e.g. gastro-intestinal bleeding or perforation, asthma, an itchy runny nose, nasal polyps (swellings inside the nose), rashes or swelling of the skin
- suffer from or have a history of peptic ulcers (ulcers in your stomach or duodenum), or bleeding in your digestive tract
- have severe heart failure, liver or kidney failure
- are in the last three months of pregnancy.

Warnings and precautions

Take special care with Naproxen

Talk to your doctor before you start to take this medicine if you:

- are elderly
- had or have bronchial asthma or allergies (like hayfever)
- suffer from any kidney problems (e.g. kidney inflammation, blood and/or protein in the urine)
- suffer from any liver or heart problems (e.g. high blood pressure, stroke, heart attack)
- have fluid retention
- suffer from any blood clotting disorders
- have a history of disease or problems with your digestion system (especially if you have any bleeding)
- have ulcerated colitis or Crohn's disease
- have systemic lupus erythematosus (SLE), or other connective tissue disorders

- have Stevens-Johnson syndrome or toxic epidermal necrolysis (severe skin problems)
- are a female and trying to get pregnant.

If you are to undergo adrenal function tests or urine tests your doctor may tell you to stop taking Naproxen in case it interferes with these tests.

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.

Other medicines and Naproxen Gastro-resistant 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 if you are taking:

- aspirin or any other NSAID (e.g. ibuprofen, cyclooxygenase-2-selective inhibitor medicines).
- any other pain killers
- medicines that could increase the risk of ulcers or bleeding in your stomach such as corticosteroids (e.g. hydrocortisone or prednisolone), anti-coagulants (e.g. heparin, warfarin) or anti-platelets (e.g. aspirin)
- aspirin/ acetylsalicylic acid to prevent blood clots
- medicines used to treat the symptoms of heartburn (antacids)
- medicines to treat high blood pressure
- ACE inhibitor medicines (e.g. ramipril)
- heart medicines (e.g. digoxin)
- ciclosporin or tacrolimus (a medicine used following organ transplants)
- quinolone antibiotics (e.g. ciprofloxacin, norfloxacin or levofloxacin)
- lithium (a drug used to treat depression)
- methotrexate (a treatment for leukaemia and rheumatoid arthritis)
- medicines to treat Type 2 diabetes (e.g. sulphonylureas)
- probenecid (a drug used to treat gout)
- diuretics ('water tablets') such as furosemide
- mifepristone in the last 8-12 days, (used to terminate a pregnancy)
- zidovudine (used to treat HIV)
- colestyramine (used to relieve diarrhoea after surgery or radiotherapy, lower cholesterol or other fats in the blood, prevent heart disease, or treat itching)
- SSRIs (used to treat depression).

Important information about some of the ingredients of Naproxen

- Patients who are intolerant to lactose should note that Naproxen tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Pregnancy and breast-feeding

- **Do not use** Naproxen in the last three months of pregnancy or during labour and delivery
- **Do not use** if you are breast-feeding
- If you are pregnant in the earlier stages, ask your doctor for advice before taking this medicine. Your doctor will decide if you should take Naproxen
- Naproxen may make it more difficult to become pregnant. You should discuss with your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

- Naproxen may cause a feeling of dizziness or "spinning", drowsiness, tiredness, difficulty in sleeping, depression or problems with your eyesight. If you are affected, do not drive or operate machinery.

3 How to take Naproxen Gastro-resistant Tablets

Always take Naproxen exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be taken with or after food, and should be swallowed whole (not to be broken or crushed) preferably with a drink of water. **Do not chew the tablets.** The tablet is coated with a gastro-resistant coat. This coat allows the tablet to pass undissolved through the stomach into the small intestine, where naproxen is released.

The recommended dose is:

Adults

- Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis
The usual dose is 500 mg - 1000 mg daily taken as 250 - 500 mg twice a day at 12-hour intervals. Where 1000 mg is needed, it is recommended that two 500 mg tablets are taken at once, either in the morning or evening.
- Acute musculoskeletal disorders and period pains

500 mg to start with, then 250 mg every 6 - 8 hours as needed. The maximum daily dose (after the first day) is 1250 mg.

- **Acute gout**
750 mg immediately, then 250 mg every 8 hours until the attack has passed.

The Elderly

- The usual adult dose is suitable. To reduce the possibility of side effects if you are elderly, you should use the minimum dose for the shortest possible time. Your doctor may monitor you for bleeding in the stomach. If you have kidney problems your doctor may recommend a reduction in dosage.

Patients with liver and kidney problems

Your doctor will decide an appropriate dose, which may be lower than for other adults. Your dose should be reviewed by your doctor at regular intervals.

Use in children

Children over 5 years of age

- **Juvenile rheumatoid arthritis**
Your doctor will calculate the appropriate dose depending on your child's body weight. The dose should be taken twice a day every 12 hours. Naproxen should not be used to treat anything else in children.

If you take more Naproxen than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause headaches, drowsiness, heartburn, indigestion or abdominal pain, feeling sick or being sick, bleeding in the digestive tract, diarrhoea, disorientation, irritation, breathing difficulties, coma, dizziness, ringing in the ears, fainting, fits, in some cases kidney and/or liver problems.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Naproxen

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

If you stop taking Naproxen

Do not stop taking your medicine without talking to your doctor first even if you feel better.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Naproxen Gastro-resistant Tablets can cause side effects, although not everybody gets them.

STOP TAKING the tablets and seek immediate

medical help if you suffer from any of the following at any time during your treatment:

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives (with symptoms such as itching, nettle rash, bruise like rash), or worsening of existing asthma
- Stevens-Johnson syndrome (severe blisters and bleeding in the mucous membranes of the lips, eyes, mouth, nasal passage, and genitals) or a skin reaction causing blistering and flaking of the skin
- pass blood in your faeces (stools/motions)
- pass black tarry stools (a symptom of bleeding in the stomach or intestines)
- vomit any blood or dark particles that look like coffee grounds.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

STOP TAKING the tablets and tell your doctor if you experience:

- indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

The following side effects have also been reported:

Most common

- feeling sick and/or being sick
- diarrhoea
- bloating and/or constipation
- abdominal pain, indigestion and/or heartburn
- inflammation of the mouth, lips, cheeks, gums or throat.

Less common

- inflammation in the lining of the stomach
- ulcers in the stomach and/or intestines
- small holes in the stomach and/or intestines (perforations)
- colitis (inflammation of the lining of the large intestine).

Very Rare

- pancreatitis (inflammation of the pancreas).

Other side effects can include:

- medicines such as Naproxen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke
- heart problems such as inflammation of the blood

vessels, water retention, high blood pressure, heart palpitations (a fluttering feeling in your heart), congestive heart failure (heart problems which can cause shortness of breath or ankle swelling) or heart failure

- kidney problems such as inflammation of the kidneys, kidney damage or kidney failure, blood in the urine or raised serum creatinine (which may cause changes in blood chemistry)
- liver problems such as abnormal liver function test results, inflammation of the liver (hepatitis), jaundice (yellowing of the skin or whites of the eyes)
- problems with the senses such as vision problems, inflammation of the optic nerve, pins-and-needles or numbness, ringing in the ears or impaired hearing
- aseptic meningitis (inflammation of the lining of the brain), especially in patients with an auto-immune disease e.g. Systemic Lupus Erythematosus (SLE) or mixed connective tissue disease; symptoms may include stiff neck, fever, disorientation, depression, confusion or hallucinations, ringing in the ears or hearing problems, dizziness and vertigo, a general feeling of being unwell, unusual tiredness or drowsiness
- eosinophilic pneumonitis (lung infection which causes difficulty in breathing and night sweats)
- blood disorders such as low numbers of red or white blood cells, low levels of calcium in the blood, high levels of potassium (which may cause abnormal heart rhythm), reduction in blood platelets (which may increase the risk of bleeding and bruising), neutropenia (which may cause fever or chills, sore throat, ulcers in your mouth or throat)
- oesophagitis (inflammation of the gullet)
- mental illnesses such as difficulty in sleeping, abnormal dreams, depression, confusion, hallucinations
- nervous system problems such as fits, dizziness, headaches, light-headedness, drowsiness, forgetfulness and difficulty concentrating
- female infertility
- sensitivity to light
- hair loss
- a general feeling of being unwell, tiredness, fever, sweating, thirst, muscle pain or weakness, bruising
- other skin rashes such as inflammatory skin eruption and red-purple swelling on the legs.

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. 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 Gastro-resistant Tablets

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

These tablets should be stored in the package or container supplied. Do not store above 25°C. Do not transfer them to another container.

Do not use Naproxen after the expiry date that is stated on the outer packaging. 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 Gastro-resistant Tablets contain:

- The active ingredient is naproxen 250 mg or 500 mg.
- The other ingredients are lactose monohydrate, maize starch, povidone, sodium starch glycolate (type A), magnesium stearate (E572), colloidal silicon dioxide, polyvinyl acetate phthalate, purified stearic acid (E570), polyethylene glycol, hydroxypropyl methylcellulose (E464), sodium alginate (E401), sodium bicarbonate (E500), purified talc (E553b), triethyl citrate, titanium dioxide (E171), antifoam AF emulsion, shellac, black iron oxide (E172), propylene glycol (E1520).

What Naproxen Gastro-resistant Tablets look like and contents of the pack:

- Naproxen 250 mg Gastro-resistant Tablets are white, round, biconvex, tablets, printed '3N3'.
- Naproxen 500 mg Gastro-resistant Tablets are white, capsule-shaped, tablets, printed '5N3'.
- The product is available in packs sizes of 10, 28, 56, and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder and company responsible for manufacture is TEVA UK Limited, Eastbourne, BN22 9AG.

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