

Package Leaflet: Information for the user

Napralief®**250 mg Gastro-resistant Tablets**

naproxen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist has told you.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- Speak to your pharmacist or doctor if your symptoms have not improved after 3 days or if they worsen
- The name of this medicine is Napralief® 250mg Gastro-Resistant Tablets. It will be referred to as Napralief® Tablet throughout this leaflet.

What is in this leaflet:**1. What Napralief® Tablets are and what they are used for****2. What you need to know before you take Napralief® Tablets****3. How to take Napralief® Tablets****4. Possible side effects****5. How to store Napralief® Tablets****6. Contents of the pack and other information****1. What Napralief® Tablets are and what they are used for**

Napralief® Tablets contain an active ingredient called naproxen. This is a non-steroidal anti-inflammatory drug (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling, and high temperature. Napralief Tablets can lessen pain, swelling, redness and heat (inflammation) and are used in adults (18-50 years) for the short-term relief of:

- muscle or joint pain, such as sprains and strains, inflammation caused by sporting injuries, lower back pain, neck pain or pain in the wrists or feet
- period pain.

2. What you need to know before you take Napralief® Tablets**Do not take Napralief® Tablets if**

- You are allergic (hypersensitive) to:
 - Naproxen, naproxen sodium or any of the other ingredients of Napralief® Tablets (listed in section 6).
 - Aspirin, other NSAIDs or any other pain relief medicines (such as ibuprofen or diclofenac).
- You have now or have ever had any problems with your stomach or gut (intestine) like an ulcer or bleeding
- You have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- You have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-steroidal anti-inflammatory drugs)
- You have severe liver or kidney problems
- You have heart problems, high blood pressure or blood coagulation disorder
- You have breathing difficulties
- You are in the last three months of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Napralief® 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 any of the following apply to you:
 - Asthma or allergies (like hayfever) or have had swelling of the face, lips, eyes or tongue in the past
 - A feeling of weakness (perhaps because of an illness) or you are an older person
 - Lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked, or itchy nose (rhinitis)
 - Problems with your kidneys or liver
 - Problems with the way that your blood clots
 - Problems with the blood vessels (arteries) anywhere in your body
 - Too much fat (lipid) in your blood (hyperlipidaemia)
 - An autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) and ulcerative colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss)
 - Are in the first 6 months of pregnancy
 - Have an infection. This medicine may hide signs of infections such as fever and pain. It is therefore, possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Skin reactions. Serious skin reactions including (Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported in association with Naproxen Tablets. Stop using Napralief® Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Napralief® Tablets.

Children and adolescents

Napralief® tablets is not recommended for use in children under 18 years of age.

Other medicines and Napralief® Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. In particular, tell your doctor or pharmacist if you are taking:

- Other pain killers, like Aspirin/acetilsalicylic acid, ibuprofen, diclofenac and paracetamol
- Medicine to stop your blood clotting, like Aspirin/acetilsalicylic acid, warfarin, heparin or clopidogrel
- A hydantoin (for epilepsy), like phenytoin
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections)
- A sulfonylurea (for diabetes), like glimepiride or glipizide
- An 'ACE inhibitor' or any other medicine for high blood pressure like cilazapril, enalapril or propranolol
- An angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan
- A diuretic (water tablet) (for high blood pressure), like furosemide
- A 'cardiac glycoside' (for heart problems), like digoxin
- A steroid (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone
- A 'quinolone antibiotic' (for infections), like ciprofloxacin or moxifloxacin
- Certain medicines for mental health problems like lithium or 'SSRIs' like fluoxetine or citalopram
- Probenecid (for gout)
- Methotrexate (used to treat skin problems, arthritis or cancer)
- Ciclosporin or tacrolimus (for skin problems or after an organ transplant)
- Zidovudine (used to treat AIDS and HIV infections)
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died) Napralief® Tablets should not be taken within 8-12 days of taking mifepristone
- Antacids (to treat heartburn)
- Colestyramine (for high cholesterol) (take naproxen 1 hour before or 4 to 6 hours after colestyramine to avoid interference with absorption).

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Napralief® Tablets.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine
- Do not take Napralief® Tablets if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.**
- You should not take Napralief® Tablets during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Napralief® Tablets can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring**
- Napralief® Tablets may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Napralief® Tablets may make you feel tired, drowsy, dizzy and cause changes in vision. If affected, do not drive or operate machinery

Napralief® Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 250mg Tablet, that is to say essentially 'sodium-free'.

3. How to take Napralief® Tablets

This product is for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. 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.

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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 (18-50 years)**Muscle, joint or tendon problems and period pain**

- The initial dose is 500mg (2 tablets), followed by 250mg (1 tablet) every 6 to 8 hours as needed

Older people

Napralief® is not recommended for those over 50 years of age.

Use in children and adolescents

Napralief® Tablets are not for use in children under 18 years of age.

Do not exceed (take more than) the recommended dose or duration (length) of treatment

Do not take for longer than 3 days unless your doctor tells you to. Check with your doctor or pharmacist if you are not sure. You should make sure that you have enough to drink (stay well hydrated) when you are taking Napralief® Tablets.

This is particularly important for people who have problems with their kidneys.

If you take more Napralief® Tablets than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Napralief® Tablets

- If you forget to take a dose, skip the missed dose then take your next dose as normal
- 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.

Medicines such as Napralief® Tablets may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

Important side effects to look out for:

Stop taking Napralief® Tablets and tell a doctor straight away if any of the following side effects happen.

You may need urgent medical treatment:**Serious stomach or gut problems, signs include:**

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea
- Ulcers or holes forming in your stomach or gut. Signs include upset stomach, stomach pain, fever, feeling or being sick
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

Severe skin reactions, signs include:

- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS). See also section 2.
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching
- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time
- Skin blistering when exposed to sunlight (porphyria cutanea tarda) seen most on arms, face and hands.

Allergic reactions, signs include:

- Sudden swelling of your throat, face, hands or feet
- Difficulty breathing, tightness in your chest
- Skin rashes, blisters or itching.

Liver problems, signs include:

- Yellowing of your skin or the whites of your eyes (jaundice)
- Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

Heart attack, signs include:

- Chest pain which may spread to your neck and shoulders and down your left arm.

Stroke, signs include:

- Muscle weakness and numbness. This may only be on one side of your body
- A suddenly altered sense of smell, taste, hearing or vision, confusion.

Meningitis, signs include:

- Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

If you notice any of the serious side effects mentioned above, stop taking Napralief® Tablets and tell your doctor straight away.

Other possible side effects:**Stomach and gut**

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.

Blood

- Blood problems, like anaemia or changes to the numbers of white blood cells.

Mental illness

- Having difficulty sleeping or changes in your patterns of dreaming
- Depression
- Confusion or seeing and possibly hearing things that are not there (hallucinations).

Nervous system

- Headache
- Fits or seizures, feeling dizzy or lightheaded or sleepy
- Pins and needles or numbness of your hands and feet
- Difficulty with your memory or concentration.

Eyes and ears

- Changes to your eyesight, eye pain
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss
- Dizziness that causes problems with your balance.

Heart and circulation

- Swelling of your hands, feet or legs (oedema). This may be with chest pains, tiredness, shortness of breath (cardiac failure)
- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain.

Chest

- Difficulty breathing, including shortness of breath, wheezing or coughing
- Pneumonia or swelling of your lungs.

Skin and hair

- Skin rashes including redness, hives, pimples and blisters on your body and face
- Bruising, itching, sweating, skin being more sensitive to the sun or hair loss.

Urinary

- Blood in your water (urine) or kidney problems.

Other

- Thirst, fever, feeling tired or generally unwell
- A sore mouth or mouth ulcers
- Muscle pain or weakness
- Problems for women in getting pregnant
- 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 Napralief® Tablets

- Keep this medicine out of the sight and reach of children
- This medicinal product does not require any special storage conditions
- Do not use this medicine after the expiry date which is stated on the carton and the blister strip. 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 Napralief® Tablets contains**

- The active substance in Napralief® Tablets is naproxen. Each tablet contains naproxen 250mg
- The other ingredients are: microcrystalline cellulose PH 101, croscarmellose sodium, povidone, magnesium stearate, methacrylic acid ethylacrylate cop