

PACKAGE LEAFLET: INFORMATION FOR THE USER

Naproxen 250 mg Gastro-resistant Tablets

Naproxen 500 mg Gastro-resistant Tablets

naproxen

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 of illness 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.

What is in this leaflet:

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

1. What Naproxen Tablets are and what they are used for

Naproxen Tablets contain a medicine called naproxen. This is a ‘Non-Steroidal Anti-Inflammatory Drug’ or NSAID. Naproxen Tablets can lessen pain, swelling, redness and heat (inflammation) and is used to treat adults for:

- Problems with your muscles, joints and tendons, like strains, back pain, ankylosing spondylitis (pain and stiffness in the neck and back) or arthritis
- Women, while having period pain.

2. What you need to know before you take Naproxen Tablets

Do not take Naproxen Tablets if you are allergic (hypersensitive) to:

- Naproxen, naproxen sodium or any of the other ingredients of Naproxen Tablets (listed in section 6).
- Aspirin, other NSAIDs or any other pain relief medicines (such as ibuprofen or diclofenac).

Do not take Naproxen Tablets if:

- You have now or have ever had any problems with your stomach or gut (intestine) like an ulcer or bleeding
- You have previously experienced bleeding or perforation in your stomach while taking NSAIDs
- You have severe problems with your kidneys, liver or heart
- You are in the last three months of pregnancy.

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

Warnings and precautions

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 Naproxen Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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.

Talk to your doctor or pharmacist before taking Naproxen Tablets 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).

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

Children and adolescents

Naproxen tablets is not recommended for use in children under 16 years of age.

Other medicines and Naproxen 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, ibuprofen, diclofenac and paracetamol
- Medicine to stop your blood clotting, like 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)
- Aspirin/ acetylsalicylic acid to prevent blood clots.

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

Pregnancy, breast-feeding and fertility

- Do not take Naproxen Tablets if you are in the last three months of pregnancy as it can 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 naproxen 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, naproxen 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.
- 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.
- Naproxen 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:

Naproxen Tablets may make you tired, drowsy, dizzy, have problems with your eyesight and balance, depressed or have difficulty sleeping. Talk to your doctor if any of these happen to you and do not drive or use any tools or machines.

Naproxen 250 mg Gastro-resistant Tablets contains sodium

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

Naproxen 500 mg Gastro-resistant Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 500 mg tablet, that is to say essentially 'sodium-free'.

3. How to take Naproxen Tablets

Always take this medicine exactly 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. 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

Muscle, joint or tendon problems and period pain

- The usual starting dose is 500 mg, followed by 250 mg tablet every 6 to 8 hours as needed.

Arthritis and ankylosing spondylitis

- The usual dose is between 500 mg and 1000 mg
- The dose can be taken all at once, or split in two and taken twice a day.

Older people and people with liver and kidney problems

Your doctor will decide your dose, it will usually be lower than that for other adults.

Use in children and adolescents

Naproxen Tablets are not for use in children under 16 years of age.

Medicines such as Naproxen Tablets may be associated (linked) with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with higher doses and prolonged (longer term) treatment.

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

Check with your doctor if you are not sure.

Swallow the tablets whole with a little water, with or after food. Do not crush or chew the tablets.

You should make sure that you have enough to drink (stay well hydrated) when you are taking Naproxen Tablets. This is particularly important for people who have problems with their kidneys.

While you are taking Naproxen Tablets your doctor will want to see you to check you are on the right dose for you and look for any side effects. This is particularly important if you are an older person.

If you take more Naproxen Tablets than you should

If you take more Naproxen 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 Naproxen 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 Naproxen 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 Naproxen 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.

Allergic reactions, signs include:

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

Severe skin reactions, signs include:

- 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.
- 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.

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 Naproxen 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 heartbeat 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naproxen 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 Naproxen Tablets contains

- The active substance in Naproxen Tablets is naproxen. Each tablet contains naproxen 250 mg or 500 mg.
- The other ingredients are: microcrystalline cellulose PH 101, croscarmellose sodium, povidone, magnesium stearate, methacrylic acid ethylacrylate copolymer (1:1) dispersion 30%, sodium hydroxide, triethyl citrate and talc.

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

500 mg tablets

Naproxen 500 mg Gastro-resistant Tablets are white colour, capsule-shaped biconvex enteric-coated tablets debossed with “500” on one side and plain on the other side.

Naproxen Tablets are supplied in Alu/PVC 4 blister packs of 14 tablets.

The pack size is 56 tablets.

250 mg tablets

Naproxen 250 mg Gastro-resistant Tablets are White colour, circular-shaped biconvex enteric-coated tablets debossed with “250” on one side and plain on the other side.

Naproxen Tablets are supplied in Alu/PVC 4 blister packs of 14 tablets.

The pack size is 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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