

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Naproxen 250mg and 500mg Tablets**

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 it is 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 is and what it is used for**

Naproxen Tablets contain a medicine called Naproxen.

Naproxen 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, gout, ankylosing spondylitis (pain and stiffness in the neck and back) or arthritis.
- Women, while having period pain.
- It can also be used in children over 5 years with rheumatoid arthritis.

**2. What you need to know before you take Naproxen Tablets****Do not take Naproxen Tablets:**

- if you are allergic (hypersensitive) to Naproxen sodium or any of the other ingredients of Naproxen Tablets (listed in section 6).
- if you are allergic to or have ever had a reaction to aspirin or another NSAID such as ibuprofen, diclofenac or meloxicam
- if you have a stomach ulcer or if you often get stomach ulcers
- if you have a duodenal ulcer (in the first part of the small intestine) or if you often get duodenal ulcers
- if you have serious liver or kidney disease
- if you are suffering or have ever suffered from bleeding in the stomach or intestines while taking NSAIDs
- You are in the last three months of pregnancy (See section 2 **Pregnancy, breast feeding and fertility**)

- if you have severe heart failure

Do not take Naproxen 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****Talk to your doctor or pharmacist before taking Naproxen Tablets if you:**

- have heart problems, have previously had a 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)
- have problems with how your blood clots
- have ever had asthma or allergies (like hayfever) or have had swelling of the face, lips, eyes or tongue in the past.
- have a feeling of weakness (perhaps because of an illness) or you are an older person.
- have lumps in your nose (polyps) or you squeeze a lot or have a runny, blocked, or itchy nose (rhinitis)
- have problems with the blood vessels (arteries) anywhere in your body, suffer from localised swelling, high blood pressure or heart failure
- have too much fat (lipid) in your blood (hyperlipidaemia)
- have problems with your kidneys or liver
- have an autoimmune condition, such as 'systemic lupus erythematosus' that causes joint pain, skin rashes and fever
- have colitis or Crohn's disease, the symptoms are inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss.
- 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. Stop using Naproxen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you are **elderly**, you may have an increased risk of side effects. Tell your doctor **immediately** if you suffer with any unusual symptoms of the stomach or bowel.

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.

**Other medicines and Naproxen Tablets**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without 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, aspirin/acetylsalicylic acid, warfarin, heparin or clopidogrel or ticlopidone
- Medicines used to treat epilepsy such as, phenytoin and hydantoin
- Sulfonamide medicines like, hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics used to treat infections.

- A sulfonyleurea (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
- Selective serotonin reuptake inhibitors such as fluoxetine or citalopram.
- Probenecid (a medicine to treat gout).
- Certain medicines to treat mental illness, such as lithium
- Methotrexate, a medicine used to treat skin conditions, rheumatoid arthritis and cancer).
- Ciclosporin or tacrolimus, medicines use to prevent transplant rejection after surgery.
- Zidovudine (used to treat AIDS and HIV infections)
- Colestyramine, a medicine used to reduce cholesterol
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died).

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.

Please note that the above medicines may be known to you by other names, often the brand names. In this section only the active ingredient or therapeutic group of the medicine is given, and not the brand name. Always thoroughly check the pack and information leaflet of the medicines you are already using for the active ingredient or therapeutic group of that medicine.

**It may still be alright for you to take Naproxen tablets and your doctor will be able to decide what is suitable for you.**

**Pregnancy, breast-feeding and fertility**

- 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.
- Do not take Naproxen if you are in the last three months of pregnancy, as it can harm your baby. 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.

- Do not take Naproxen if you are in the last three months of pregnancy, as it can harm your baby. 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.
- 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 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 may make you feel 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 Tablets contain Lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**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.

**Method of administration:**

Naproxen Tablets should be swallowed whole with a little water, with or after food. You should make sure that you have enough to drink (stay well hydrated) when you are taking Naproxen. This is particularly important for people who have problems with their kidneys.

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

The recommended doses are:

**Children over 5 years, rheumatoid arthritis**

- The usual dose is 10 mg/kg body weight each day.
- The dose is split into two and given 12 hours apart.

**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 into two doses and can be taken twice a day.

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**Gout**

- The usual starting dose is 750 mg, followed by 250 mg tablet every 8 hours as needed.

**The elderly and people with liver and kidney problems**

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

**If you take more Naproxen Tablets than you should**

Medicines such as Naproxen Tablets may be 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.**

If you take more Naproxen Tablets than you should, talk to your doctor or go to the hospital straight away. Take the pack with you.

**Symptoms of overdose** include headache, heartburn, feeling or being sick, indigestion, epigastric pain (upset stomach), bleeding of the stomach or intestines, diarrhoea, disorientation, excitement, drowsiness, dizziness, ringing or buzzing in the ears, fainting, temporary changes to liver or kidney functions, difficulty breathing, reducing the time it takes for your blood to clot.

**If you forget to take Naproxen Tablets**

If you have missed a dose, continue in accordance with your doctor's prescription. Never take a double dose of Naproxen Tablets to make up for a forgotten dose. 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 can cause side effects, although not everyone will get them.

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

**Serious side effects: Stop taking Naproxen 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 in breathing, tightness in your chest.
- Skin rashes, blisters or itching.
- Widespread rash.
- High body temperature.

**Severe skin rashes, signs include:**

- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes (Stevens Johnson Syndrome or Toxic epidermal necrolysis)
- Fever, headache, cough and aching body may happen at the same time.
- Blistering of skin when exposed to sunlight (porphyria cutanea tarda) seen most on arms, face and hands.
- 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.
- Liver enzyme elevations.

**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 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 abnormalities (eosinophilia).
- Blood problems like, anaemia or changes to the numbers of white blood cells

**Mental illness**

- Having difficulty in sleeping or change 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 light-headed 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 in 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.
- 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.
- Enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS).

**Reporting of side effects**

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. You can

also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Tablets****Keep this medicine out of the sight and reach of children**

Do not use Naproxen Tablets after the expiry date which is printed on the pack.

The expiry date refers to the last day of that month

- Naproxen Tablets should be kept in their original packaging to protect them from light. Store below 25°C.
- Do not use Naproxen Tablets after the expiry date which is printed on the pack. The expiry date refers to the last day of that month.
- Do not use Naproxen Tablets if you notice any visible signs of deterioration.
- 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 contains**

- The active substance is naproxen. Each tablet contains either 250 mg (milligrams) or 500 mg of naproxen
- The other ingredients are sodium lauryl sulphate, lactose, maize starch, crospovidone and magnesium stearate

**What Naproxen looks like and contents of the pack**

Naproxen 250 mg tablets: White, to off white, circular flat bevelled edge tablets with 'N' breakline '250' on one side and BL on the other.

Naproxen 500 mg tablets: White to off white, oblong tablets with 'N' breakline '500' on one side and BL on the other.

Naproxen 250 mg tablets are supplied in Securitainers of 28, 56, 250 tablets and blisters of 28, 56, 84 and 112 tablets.

Naproxen 500 mg tablets are supplied in Securitainers of 28, 56, 100, 500 tablets and blisters of 28, 56, 84 and 112 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR

**Manufacturer**

Rx Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR, United Kingdom

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