

PACKAGE LEAFLET: INFORMATION FOR THE USER
NAPROXEN TABLETS 250mg and 500mg
 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Naproxen can relieve pain, stiffness and inflammation caused by: rheumatoid arthritis, osteoarthritis, ankylosing spondylitis (arthritis of the spine and pelvis) and juvenile rheumatoid arthritis.

It is also used to treat acute gout and acute musculoskeletal disorders such as sprains, strains, trauma, lower back pain, neck pain and inflammation of tendons and muscles.

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

Do not take Naproxen Tablets if you:

- Are allergic to naproxen or any other ingredients of this medicine (listed in section 6)
- 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
- Have a history of stomach bleeding or perforation which may be related to the use of NSAIDs (Mefenamic acid, ibuprofen, diclofenac) or aspirin
- Have a history of allergy to aspirin, ibuprofen or NSAIDs, which includes attacks of asthma, swelling of the nose and throat, skin rashes or a runny nose
- Suffer from severe kidney, heart or liver disease
- Are in the last trimester of your pregnancy.

If you go into hospital or to see a doctor or dentist, tell them you are taking Naproxen Tablets.

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 this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Naproxen Tablets if you:

- Suffer from asthma or allergies (like hay fever) or have had swelling of the face, lips, eyes or tongue in the past
- Feel weak (perhaps because of an illness) or you are an older person
- Have lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked or itchy nose (rhinitis)
- Have problems with your kidneys or liver
- Have problems with the way your blood clots
- Have problems with the blood vessels (arteries) anywhere in your body
- Have too much fat (lipid) in your blood (hyperlipidaemia)
- Have an autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) and colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss) Have heart problems (high blood pressure, previous stroke).

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 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 Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Especially:

- Other pain killers like aspirin, ibuprofen, diclofenac and paracetamol
- A diuretic (water tablet used for high blood pressure), like furosemide
- Medicines for high blood pressure
- Digoxin for heart conditions
- Lithium or SSRIs (Selective Serotonin Reuptake Inhibitors) such as fluoxetine or paroxetine used for treatment of depression
- Prednisolone, hydrocortisone and dexamethasone a steroid treatment for inflammation
- Methotrexate used to treat rheumatoid arthritis
- Ciclosporin, tacrolimus which are medicines used to suppress the immune system
- Ciprofloxacin, sulphonamides such as sulphamethoxazole, antibiotics used to treat bacterial infections
- Mifepristone used in pregnancy terminations (at any time within the last 12 days)
- Zidovudine used for the treatment of AIDS and HIV infections
- Anti-inflammatory pain killers such as ibuprofen or ibuprofen preparations that can be bought without a prescription
- Phenytoin used to treat epilepsy
- Gliclazide or glibenclamide (sulphonylureas) used to treat diabetes
- Probenecid used to treat gout
- Aspirin/acetylsalicylic acid, clopidogrel, warfarin, heparin, ticlopidine, dipyridamole which are anti-platelet agents used to prevent blood clots
- Colestyramine used to treat high levels of cholesterol in the blood
- Medicines used as antacids
- Angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan.

Naproxen Tablets with food and drink

Naproxen Tablets should only be taken by mouth. Always take the tablets with plenty of water, preferably with food.

Try to take them at the same time every day.

Pregnancy, breast-feeding and fertility

Pregnancy

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

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.

Breast-feeding

Naproxen does pass into the mother's milk; therefore breast-feeding should be avoided if taking Naproxen Tablets.

Fertility

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

Undesirable effects such as dizziness, drowsiness, vertigo, difficulty sleeping, depression, tiredness and visual disturbances are possible after taking NSAIDs. If you are affected do not drive or operate machinery.

Naproxen tablets contain lactose, sunset yellow (E110) and sodium

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

Sunset yellow (E110) may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'

3. How to take Naproxen Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The lowest effective dose should be used for the shortest possible time.

The recommended doses are given below. Check with your doctor if you are not sure why you have been prescribed this medicine.

For rheumatoid arthritis, osteoarthritis and ankylosing spondylitis:

250-500mg taken at 12 hour intervals.

Acute musculoskeletal disorders: 500mg to start with, followed by 250mg every 6-8 hours. Do not take more than 1250mg (i.e. five 250mg tablets) in any 24 hour period.

Acute gout: 750mg to start with, followed by 250mg every 8 hours until the attack has passed.

The elderly:

Elderly patients are more likely to experience side effects. Therefore treatment should be started on the lowest possible dose for the shortest possible duration. Your doctor should monitor your condition regularly.

----- 180 x 310 mm -----

FRONT SIDE PRINTING

ARTWORK DETAIL LABEL

Product	Naproxen Tablets - 250 mg & 500 mg		
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert
Dimension	180 x 310 mm	Pack	----
New Item Code	1048246	Old Item Code	1047062
Colour Shades	■ BLACK	No. of Colours	1
Change Control No.	PC-TSG/2022/383 Record Number: 365359		Artwork Version 11.0
Design/Style	Front & Back Printing. To be supplied unfold.		
Substrate	60 GSM Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.		
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.			

Use in children

If Naproxen Tablets are prescribed for a child make sure that the tablets are taken as instructed by the doctor. Naproxen is not recommended for children under 16 years of age for use other than in the treatment of juvenile rheumatoid arthritis. For juvenile rheumatoid arthritis a dose of 10mg per kg body weight per day should be given in two doses, once every 12 hours.

You should have enough to drink to stay well hydrated while taking this medicine, particularly important for people having kidney problems.

If you take more Naproxen Tablets than you should

If you accidentally take too many Naproxen Tablets, 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:

If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:

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 rashes, signs include:

- A severe rash that develops quickly, with blisters or peeling of skin and possibly blisters in your mouth, throat or eyes. 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.

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').

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 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 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.

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 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 Tablets

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package to protect from light.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Do not use this medicine if you notice 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 Tablets contain**

The active substance is Naproxen
The other ingredients are: Lactose Monohydrate
Maize Starch
Sodium lauryl sulfate
Crospovidone
Magnesium Stearate
Quinoline yellow (E104)
Sunset yellow (E110)

What Naproxen Tablets look like and contents of the pack**Description:**

Naproxen Tablets 250 mg: Pale yellow colored flat radius edge tablet with break line on one face and plain on the other face with mottled surface.

Naproxen Tablets 500 mg: Pale yellow colored oblong tablet with break line on one face and plain on the other face with mottled surface.

Contents of pack: Tubes

1. Polypropylene tubes fitted with low density polyethylene caps
 2. Tracer packs: Child resistant containers consisting of polypropylene tubes fitted with high density polyethylene caps
- Pack sizes: (Naproxen Tablets 250 mg): 28, 56 or 250 tablets.
(Naproxen Tablets 500 mg): Packs of 28, 56, 100 or 500 tablets.
3. Blister packs consisting of clear PVC and hard temper aluminium foil contained in a carton

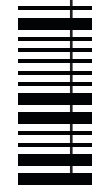
Pack sizes: 28

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre
Dwight Road, Watford
WD18 9SS United Kingdom

This leaflet was last revised in 12/2022.



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BACK SIDE PRINTING

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ARTWORK DETAIL LABEL

Product	Naproxen Tablets - 250 mg & 500 mg			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	180 x 310 mm	Pack	----	
New Item Code	1048246	Old Item Code	1047062	
Colour Shades	■ BLACK	No. of Colours	1	
Change Control No.	PC-TSG/2022/383 Record Number: 365359		Artwork Version	11.0
Design/Style	Front & Back Printing. To be supplied unfold.			
Substrate	60 GSM Paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

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