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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.

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.

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 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.

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)

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.

Information on sodium content

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.

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180 x 310 mm

FRONT SIDE PRINTING

Non - Printing Color

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	1050905	Old Item Code	1048246		
Colour Shades	<div> </div> BLACK			No. of Colours	1
Change Control No.	PC-ODF/2024/412 - Record Number: 426453			Artwork Version	12.0
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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