

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### NAPROXEN 250 mg TABLETS

### NAPROXEN 500 mg 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. Do not pass it on to others. It may harm them, even if their symptoms 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 belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in joints and muscles.

Naproxen tablets are used to treat:

- diseases of joints such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis. Naproxen cannot cure arthritis but is used to give relief of some symptoms such as inflammation, swelling, stiffness and joint pain.
- attacks of gout
- muscle and bone disorders such as cervical spondylitis, low back pain, strains and sprains, muscular pain and stiffness (fibrositis) and inflammation of tendons (tenosynovitis).
- It is also used to treat painful menstrual periods.

## **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 (see 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:**

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 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.

#### **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 gliclazide 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.

#### **Taking Naproxen Tablets with Food and Drink**

Naproxen Tablets should be taken preferably with or after food.

#### **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 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.
- 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.

#### **Important information about some of the ingredients of Naproxen Tablets**

Naproxen Tablets contain lactose monohydrate (milk sugar); 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

Medicines such as Naproxen 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.**

Always take Naproxen Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For oral administration (by mouth)  
Swallow the tablets whole with a little water, with or after food.

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 elderly.

#### Adults

- **Rheumatoid arthritis, osteoarthritis 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.

- **Gout**

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

- **Muscle, joint or tendon problems and period pain**

The usual starting dose is 500mg as a single dose then 250mg tablet every 6-8 hours as necessary. Up to a maximum of 1250mg a day may be given after the first day.

#### Children (over 5 years)

- **For juvenile rheumatoid arthritis:** 10mg/kg/day taken in 2 doses at 12-hour intervals.

Naproxen is not recommended for use in any other indication in children under 16 years of age.

#### 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.

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

Contact your doctor, pharmacist or nearest hospital casualty department **immediately** if you have taken more tablets than you should. Take the medicine pack with you.

**Symptoms of overdose** are headache, feeling or being sick, heartburn, epigastric pain (upset stomach), diarrhoea, bleeding of the stomach or intestines, disorientation, temporary changes to liver functions, reducing the time it takes for your blood to clot, stopping breathing, body produces too much acid, unconsciousness, drowsiness, dizziness, ringing or buzzing in the ears, fainting, fits and excitation.

#### If you forget to take Naproxen Tablets

If you forget to take your tablets, take your next dose as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for one you have missed.

#### If you stop taking Naproxen Tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

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 Tablets can cause side effects, although not everybody gets them.

Medicines such as Naproxen 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 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 sometimes fatal particularly in elderly. 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 your 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, depression, vertigo, drowsiness, 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
- gastritis (an inflammation of the lining of the stomach)
- dry mouth
- throat irritation
- decreased appetite
- stomach ache
- feeling sick or being sick
- constipation
- diarrhoea
- wind
- inflammation of the food pipe (oesophagus)

Side effects on the gut can be fatal, particularly in the elderly.

### **Blood**

- a reduction in the number of platelets (thrombocytopenia)
- decreased platelet aggregation
- an increase or decrease in white blood cells
- a reduction of the quantity of the oxygen-carrying pigment haemoglobin in the blood (anaemia) caused by decreased production (aplasia) or increased destruction (haemolysis) of red blood cells
- high levels of potassium in the blood (hyperkalaemia) or inflammation of blood vessels (vasculitis).

### **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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme

Website: [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 out of the sight and reach of children.

Do not store above 25°C.

Store in the original package.

Do not use Naproxen tablets after the expiry date which is stated on the label/carton/foil. The expiry date refers to the last day of that month.

HDPE Bottle: Use within 3 months of first opening the Bottle.

Do not throw 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. Each tablet contains either 250mg or 500mg of the naproxen.

The other ingredients are

lactose monohydrate

maize Starch

polyvinylpyrrolidone ( povidone K 30 )

magnesium stearate (E572)

### **What Naproxen tablets look like and contents of the pack**

Naproxen 250mg Tablets: White to off white, circular, flat faced bevelled edge, uncoated tablet with inscription 'AP' on one side and break line on the other side

Naproxen 500mg Tablets: White to off white, capsule shaped, biconvex uncoated tablet with inscription ' AR ' on one side & break line on other side.

The Naproxen Tablets are available in containers of 1000,500,250,100,84,70,56,42,28,21,15 and 14 tablets and in blister packs of 84,70,56,42,28,21,15 and 14 tablets.

HDPE bottle packs for 500mg: 250's and 500's (for hospital use only)

Not all the packs are marketed.

### **Marketing Authorisation Holder and Manufacturer**

Accord Healthcare Limited

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