Read all of this leaflet carefully before you start taking this medicine.
- 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 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.

In this leaflet:
1. What Naproxen tablets are and what they are used for
2. Before you take Naproxen tablets
3. How to take Naproxen tablets
4. Possible side effects
5. How to store Naproxen tablets
6. Further 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. BEFORE YOU TAKE NAPROXEN TABLETS

Do not take Naproxen tablets:
- if you are allergic (hypersensitive) to naproxen or to any of the other ingredients of Naproxen Tablets (see section 6).
- if you are in the last three months of pregnancy or if you are breast-feeding
- if you are allergic to aspirin or other non-steroidal anti-inflammatory medicines (NSAIDs), or you have developed signs of asthma (wheezing), runny nose, swelling of the skin or rash when taking these medicines
- if you have or have had stomach or duodenum (gut) ulcers
- if you have severe liver, kidney (not receiving dialysis) or heart failure
- if you have had bleeding in the stomach or intestines (gastrointestinal bleeding)
- if you have a bleeding disorder such as cerebro-vascular bleeding
- if you have haemorrhoids or bleeding from your back passage (anus)
If you are not sure about any of the above conditions, please ask your doctor or pharmacist before taking Naproxen.

**Take special care with Naproxen Tablets:**
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.

Check with your doctor or pharmacist before taking Naproxen tablets:
- If you gain hypersensitivity reactions including skin rashes, lesions etc., then discontinue treatment.
- If you use other non-steroidal anti-inflammatory medicines (NSAIDs) or any medication which may cause bleeding or ulcers in the stomach
- If you have a history of gastrointestinal disease e.g. ulcerative colitis, Crohn’s disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss)
- If you drink alcohol
- If you have or have had liver or kidney problems
- If you have or have had bronchial asthma or allergic disease (like hay fever) or have had swelling of the face, lips, eyes or tongue in the past.
- If you have feeling of weakness (perhaps because of an illness) or you are elderly.
- If you have lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked, or itchy nose (rhinitis).
- If you have problems with the way that your blood clots.
- If you have problems with the blood vessels (arteries) anywhere in your body.
- If you have too much fat (lipid) in your blood (hyperlipidaemia).
- If you have systemic lupus erythematosus (SLE, causes joint pain, skin rashes and fever) or other connective tissue disorders e.g. rheumatoid arthritis (RA)
- If you are a women trying to become pregnant or undergoing investigation of infertility
- 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 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.
- If you are elderly or frail, you have a higher risk of getting side effects, especially from the stomach. If you experience any unusual symptoms from the stomach you must tell your doctor about it.
- Rarely, naproxen tablets may cause eye problems (e.g. visual disorders). Where visual disorders occur in patients during treatment with naproxen, ophthalmologic examination should be carried out.

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

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. Especially:
• Other painkillers such as aspirin, ibuprofen, diclofenac and paracetamol or COX II inhibitors
• Medicines which thin the blood or which prevent blood clotting such as warfarin, heparin or clopidogrel
• A steroid (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone, and corticosteroids (medicines used for arthritis). Please tell your doctor or pharmacist, if you stop taking steroids whilst taking naproxen.
• Diuretics (“water tablets”) (for high blood pressure), like furosemide
• ACE inhibitors or any other medicine for high blood pressure like cilazapril, enalapril or beta blockers (e.g. propranolol).
• An angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan.
• Ciclosporin or tacrolimus (for skin problems or after an organ transplant).
• Sulphonamide medicines like hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections) or quinolone antibiotics (medicines used 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).
• Antacids (medicines used to treat acidity)
• Cholestyramine (medicines used to lower cholesterol in blood)
• Hydantoins like phenytoin (medicines for epilepsy).
• Sulphonylureas (oral anti-diabetic drugs) like glimepiride or glipizide.
• Cardiac glycosides (for heart problems), like digoxin.
• Zidovudine (used to treat AIDS and HIV infections).
• Bisphosphonates (e.g. Alendronic acid) (used to treat osteoporosis or other bone diseases)
• 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.

Taking Naproxen Tablets with Food and Drink

Naproxen Tablets should be taken preferably with or after food.

Pregnancy and breast-feeding

If you are pregnant or planning to become pregnant, ask your doctor or pharmacist before you use any medication. During the first six months of pregnancy, you should only use Naproxen tablets if your doctor says it is necessary. During the last three months of the pregnancy you must not take Naproxen Tablets, as it may harm you and the unborn child and it may cause delayed or prolonged labour. If you are breast-feeding, you should not take Naproxen Tablets.

Driving and using machines

Naproxen may make you feel dizzy, drowsy or tired and may cause problems with your eyesight and balance, depressed or have difficulty sleeping. Make sure you are not affected before you drive or operate machinery.

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.

**Tests**
If you need to carry out any blood or urine tests or adrenal function test tell your doctor that you are taking Naproxen Tablets. The tablets may need to be stopped 48 hours before a test, as they may interfere with the results.

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.

**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**
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.
- Nervousness, euphoria, low body temperature
- worsening of Parkinson’s disease

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
- Skin rash, red scaly rash on the face, itchiness (urticaria), bruising, bluish/black marks or spots on the skin,
- Tender bruise like swellings (erythema nosodum),
- Swelling of the neck and face (angioedema), redness of the skin (erythema multiforme),
- Blistering of hands or feet (Stevens Johnson syndrome),
- Pus containing spots, peeling skin (epidermal necrolysis), rare reactions due to exposure to light including inflammation of the skin and blistering eruptions (pseudoporphyria or epidermolysis bullosa-like reactions),
- Swelling of the hands or feet (peripheral oedema), sweating,
- Skin being more sensitive to the sun

Hair
- Loss of hair (alopecia).

Urinary
- Blood and protein in your water (urine)
- Kidney disease or failure (may cause changes in the need to or amount of urine).
- Abnormally frequent urination

Other
- Thirst, fever, feeling tired or generally unwell.
- A sore mouth or mouth ulcers.
- Muscle pain or weakness.
- Stiff nose (rhinitis)
- High blood levels of transaminases, alkaline phosphatises, bilirubin levels, serum creatinine.
- 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.

5. **HOW TO STORE NAPROXEN TABLETS**

Keep out of the reach and sight of children.
Do not store above 25ºC.
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.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **FURTHER 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.
Not all the packs are marketed.

**Marketing Authorisation Holder and Manufacturer**
Accord Healthcare Limited
Sage House,
319, Pinner Road,
North Harrow, Middlesex,
HA1 4HF, UK

This leaflet was last approved in {06/2013}