

PACKAGE LEAFLET: INFORMATION FOR THE USER

NALGESIN

NALGESIN S 275 mg Film-coated tablets

NALGESIN F 500 mg Film-coated tablets

NAPROXEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What NALGESIN is and what it is used for
2. Before you take NALGESIN
3. How to take NALGESIN
4. Possible side effects
5. How to store NALGESIN

1. WHAT NALGESIN IS AND WHAT IS IT 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.

NALGESIN tablets are used to treat:

- diseases of joints such as **rheumatoid arthritis (including in children), 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**
- **painful periods**

2. BEFORE YOU TAKE NALGESIN

Do not use NALGESIN if:

- are in the last three months of pregnancy or if you are breast feeding
- are allergic to naproxen or to any of the other ingredients of NALGESIN tablets

- 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
 - have or have had stomach or duodenum (gut) ulcers, bleeding in the stomach or intestines (gastrointestinal bleeding) or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
 - have severe liver, kidney or heart failure
- If you are not sure about any of the above conditions, please ask your doctor.

Check with your doctor before taking NALGESIN tablets if you:

- use other non-steroidal anti-inflammatory medicines (NSAIDs) or any medication which may cause bleeding or ulcers in the stomach
- have a history of gastrointestinal disease e.g. ulcerative colitis, Crohn's disease
- smoke
- drink alcohol
- are elderly
- have or have had high blood pressure or any liver, kidney or heart problems
- have or have had bronchial asthma, other breathing problems or nasal polyps
- have systemic lupus erythematosus or other connective tissue disorders
- have a blood clotting disorder
- are a women trying to become pregnant or undergoing investigation of infertility.

Other warnings

- 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.
- Taking a painkiller for headaches too often or for too long can make them worse.
- NALGESIN tablets may hide the symptoms of an infection.

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 NSAIDs such as aspirin or COX II inhibitors
- medicines which thin the blood or which prevent blood clotting (e.g. heparin or warfarin)
- corticosteroids (e.g. prednisolone), if needed the doctor will reduce the dose of the steroid slowly and monitor for side effects.
- diuretics ("water tablets") (e.g. furosemide)
- medicines to treat high blood pressure (e.g. captopril, ramipril or propranolol, losartan or candesartan)
- ciclosporin or tacrolimus
- mifepristone – do not take NSAIDs 8-12 days after mifepristone
- SSRI antidepressants
- zidovudine
- quinolones (e.g. ciprofloxacin)
- probenecid
- methotrexate
- bisphosphonates
- colestyramine (take naproxen 1 hour before or 4 to 6 hours after colestyramine to avoid interference with absorption)
- lithium

- hydantoin (e.g. phenytoin)
- sulphonamides (e.g. sulfamethoxazole)
- sulphonylureas (e.g. glibenclamide or gliclazide)
- cardiac glycosides (e.g. digoxin).

Pregnancy and breast-feeding

Naproxen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

You should not take Naproxen in the first 6 months of pregnancy and must not take Naproxen in the last 3 months of pregnancy or during labour.

If you are breast-feeding, you should not take NALGESIN tablets.

Driving and using machines

Naproxen may make you feel dizzy, drowsy or tired and may cause blurred vision. Make sure you are not affected before you drive or operate machinery.

Sugar intolerance

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Tests

If you need any blood or urine tests tell your doctor you are taking NALGESIN tablets. The tablets may need to be stopped 48 hours before a test, as they may interfere with the results.

3. HOW TO TAKE NALGESIN

Always take NALGESIN tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow **with or after food**.

Dose

Your doctor should prescribe as low a dose as possible. This will reduce any side effects you may experience.

Adults

- **Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis**
500mg-1g a day in two doses at twelve hour intervals. If 1g is needed this can be given as two 500mg doses or as a single dose.
- **Attack of gout**
Initially 750mg as a single dose then 250mg every 8 hours until the attack has passed.
- **Muscle and bone disorders**
Initially 500mg as a single dose then 250mg every 6-8 hours as necessary. Up to a maximum of 1250mg a day may be given after the first day.

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Children over 5 years for juvenile rheumatoid arthritis

10mg per kg of body weight a day, taken in two doses at twelve hourly intervals.

Elderly

Dosage may be reduced in the elderly.

If you take more NALGESIN tablets than you should

It is important not to take too many tablets. Contact your doctor, pharmacist or nearest hospital casualty department **immediately** if you have taken more tablets than you should.

Symptoms of overdose are headache, feeling or being sick, heartburn, diarrhoea, disorientation, bleeding of the stomach or intestines, unconsciousness, drowsiness, dizziness, ringing or buzzing in the ears, fainting, fits and excitation.

If you forget to take NALGESIN tablets

If you forget to take your tablets, take your forgotten 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, NALGESIN tablets can cause side effects, although not everybody gets them. If any of the side effects get worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Stop taking NALGESIN tablets and contact your doctor immediately if you

- have indigestion, heartburn, pains in your stomach or other abnormal stomach symptoms, feeling or being sick (you may have an ulcer or inflammation in the stomach or gut)
- pass blood in your faeces (stools/motions) or black tarry looking stools (signs of bleeding and perforation of the stomach and intestines).
- vomit any blood or dark particles that look like coffee grounds
- have an **allergic reaction**:
- swelling of the face, mouth, tongue, airways or body
- skin reactions including: hives (pale/red raised skin with severe itching), blistered skin, itchy skin rash, blood spots, bruising or discolouring of the skin, raised purple rashes, red skin patches, a severe rash with reddening, peeling and swelling of the skin that resembles burns, bumpy rashes, blisters, dermatitis (skin shedding, itching, swelling)
- difficulty breathing or wheezing, coughing up blood.

Tell your doctor if you notice any of the following side effects

The most commonly observed adverse events are gastrointestinal in nature. Feeling sick, being sick, diarrhoea, wind, constipation and worsening of colitis and Crohn's disease have been reported following administration. Water retention (may cause swelling in the limbs), high blood pressure and heart failure have been reported in association with NSAID therapy.

Common (affects 1 to 10 users in 100)

confusion, headache, ringing in the ears, changes in vision (you should go for an eye test if you notice changes in vision), tiredness, drowsiness, dizziness, rashes.

Uncommon (affects 1 to 10 users in 1,000)

depression, irregular heartbeat (palpitations), abnormal dreams, forgetfulness, difficulty concentrating, sensitivity of the skin to light (may cause blistering), difficulty sleeping.

Rare (affects 1 to 10 users in 10,000)

high blood potassium levels (causing irregular, slow heart beat, feeling sick), hair loss, jaundice (yellow skin or eyes), hearing difficulties, inflammation of blood vessels (causing fever, swelling and general unwellness), worsening of asthma, muscle weakness/pain, ulcers on the inner cheeks, gums and tongue, hepatitis - sometimes fatal (symptoms include feeling tired, loss of appetite, feeling or being sick and pale coloured stools)

Very rare (affects less than 1 user in 10,000)

changes in the numbers and types of blood cells (if you develop sore throats, nose bleeds or infections consult your doctor), anaemia (may cause fainting, chest pain, breathlessness), fits, aseptic meningitis (may cause fever, feeling or being sick, disorientation, headache, neck stiffness and sensitivity to light), severe skin rash with flushing, blisters or ulcers (Stevens-Johnson syndrome), blisters or sores on the skin, kidney damage or infection (may cause blood in the urine, decrease in amount of urine passed, feeling or being sick), inflammation of the pancreas; pancreatitis (causing fever, stomach pain, sickness). Medicines such as naproxen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Not Known (frequency cannot be estimated from the available data) low amounts of white cells in the blood (may cause fever or frequent infections), runny nose, lowered female fertility (see section 2), sensing things that are not there, high blood creatinine levels seen in blood tests, kidney failure, kidney disease (may cause changes in the need to or amount of urine), thirst, fever, inflammation in the eye (causing eye pain or changes in vision), tingling or "pins and needles", a spinning sensation, abnormal liver function seen in tests, worsening of Parkinson's disease, general feeling of discomfort and illness, swelling of the hands and feet, swelling in the eye (causing headaches or blurred vision).

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NALGESIN

Keep out of the reach and sight of children.

Store below 25°C in a dry place. Protect from light.

Do not use NALGESIN tablets after the expiry date which is stated on the label/carton/bottle. 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.