Package leaflet: Information for the user

Naproxen 25 mg/ml oral suspension

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 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. See section 4.

What is in this leaflet

1. What Naproxen is and what it is used for

Naproxen oral solution contains as an active substance naproxen which is a 'Non-Steroidal Anti Inflammatory Drug' or NSAID. Naproxen alleviates inflammation and pain by reducing the formation of mediators causing pain and inflammation in the body .

Therapeutic uses of this medicine

Naproxen is used in the treatment of inflammation and pain in the following diseases and conditions: rheumatoid arthritis, ankylosing spondylitis, osteoarthrosis, acute gout, acute musculoskeletal disorders, and menstrual pain.

This medicine may also have been prescribed by a doctor for some other diseases than those mentioned in this package leaflet.

2. What you need to know before you take Naproxen

Do not take Naproxen, if you

- have a history of asthma, rhinitis, nasal polyps or rashes associated with the use of acetylsalicylic acid (aspirin) or other NSAIDs
- you are allergic to naproxen, acetylsalicylic acid or other anti-inflammatory analgesics or any of the other ingredients of this medicine (listed in section 6).
- have gastric or duodenal ulcer
- have a history of gastric or duodenal ulcer or bleeding that have recurred at least once
- have a history of gastrointestinal perforation or bleeding (e.g. black or bloody stools, blood in vomit, anaemia) in connection with the use of anti-inflammatory analgesics
- have a condition predisposing to gastrointestinal bleedings
- are in your last three months of pregnancy
- have severe kidney, liver or heart failure.

Warnings and precautions

Talk to your doctor before taking Naproxen, if you
- have heart, kidney or liver failure or liver disease
- have coronary artery disease
- have blood circulation disorders in the extremities or brain
- have uncontrolled or poorly treated high blood pressure
- have unexplained stomach pain or anaemia (low blood haemoglobin) or if you have noticed blood in your stools or your stools are black
- have a gastrointestinal disease, such as ulcerative colitis (*colitis ulcerosa*) or Crohn's disease
- have an autoimmune condition, such as systemic lupus erythematosus (SLE)
- have blood coagulation disorder, bleeding disorder or if you are taking medicines that prevent blood coagulation and formation of blood clots
- have asthma or allergies or have had swelling of the face, lips, eyes or tongue in the past
- have rhinitis or a history of nasal polyps
- are an older person.

The use of anti-inflammatory analgesics, such as Naproxen, may be associated with a slightly increased risk of a heart attack ("myocardial infarction") or stroke. All risks are increased at high doses in long-term use. Do not exceed the recommended dose and duration of treatment.

If you have a heart disease or if you have had a stroke, or if you have risk factors (e.g. high blood pressure, diabetes, high blood cholesterol level or smoking habit) predisposing to these diseases, you should discuss your treatment with a doctor or pharmacist.

If you develop visual disturbances during Naproxen treatment, you should stop the treatment and have an ophthalmological examination.

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.

Please tell your doctor if you have any other diseases or allergies.

Other medicines and Naproxen

Tell your doctor if you are taking, have recently taken or might take any other medicines. This applies to prescription-only medicines, over-the-counter medicines, herbal medicinal preparations and natural remedies.

The efficacy of certain medicines or Naproxen may change or you may experience adverse effects if you use these medicines concomitantly. Such medicines include e.g.:
- medicines that prevent blood coagulation and formation of blood clots (e.g. **warfarin, heparin or clopidogrel**), because **concomitant use increases the risk of bleeding. Combination use should be avoided**.
- certain antidepressants (e.g. citalopram, fluoxetine, paroxetine, sertraline) which belong to the so-called selective serotonin reuptake inhibitors
- acetylsalicylic acid (aspirin) and other anti-inflammatory analgesics.
- aspirin / acetylsalicylic acid to prevent blood clots. If you use a low daily dose of acetylsalicylic acid (e.g. 100 mg) for prevention of blood clots, the dose must be taken at least one hour before you take Naproxen.
- lithium (for bipolar disorder)
- digoxin (for heart diseases)
- corticosteroids taken by mouth (e.g. prednisolone or dexamethasone for alleviation of inflammation)

- methotrexate (for rheumatic and cancer diseases)
- certain immunosuppressive medicines (e.g. ciclosporin and tacrolimus)
- certain antibiotics (e.g. aminoglycosides, quinolones)
- probenecid (for gout)
- zidovudine (for HIV and AIDS)
- mifepristone (used to end pregnancy or to bring on labour if the baby has died)
- hydantoin medicines (e.g. phenytoin, for epilepsy)
- sulfonamide medicines (e.g. hydroclorothiazide, acetazolamide, indapamide for diuretic treatment and sulfonamide antibiotics for infections)
- sulfonylurea medicines (e.g. glimepiride or glipazide, for diabetes)
- bisphosphonates (for prevention and treatment of bone loss)
- certain antihypertensive medicines (e.g. betablockers like propranolol, ACE inhibitors like enalapril and angiotensin receptor antagonists like candesartan or losartan)
- water tablets (diuretics, e.g. furosemide).

Naproxen with food, drink and alcohol

You should refrain from alcohol consumption while taking NSAIDs.

Naproxen oral suspension should preferably be taken with or after food. Ingestion of a small amount of another liquid is recommended after taking the medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take Naproxen if you are in the last 3 months of pregnancy as it could 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.

Naproxen is excreted in very small amounts in breast milk. The use of naproxen is not recommended during 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 to become pregnant.

Driving and using machines

Naproxen does not usually affect the ability to drive or use machines. Some patients may experience tiredness, visual disturbances or lack of concentration after using this medicine. If these symptoms occur, driving a car and using machines should be avoided.

Naproxen contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, sorbitol and sodium

Naproxen oral suspension contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicine contains 400 mg/ml sorbitol. Daily doses as per instructions yield 1.6 g – 20 g sorbitol. Sorbitol may have a mild laxative effect. The energy content is 2.6 kcal/g sorbitol. If your doctor has told you that you have an intolerance to some sugars, discuss with your doctor before taking this medicine.

This medicine contains 24 mg sodium (main component of cooking/table salt) in each 30 ml dose. This is equivalent to 1,2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Naproxen

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Naproxen oral suspension should preferably be taken with or after food. Ingestion of small amount of another liquid is recommended after taking the medicine.

Adults:

The recommended dose is 250–500 mg (10–20 ml) twice a day based on the individual need.

For arthritis (e.g. morning stiffness): a single dose of 500–750 mg (20–30 ml) in the evenings may be adequate.

For acute gout: the recommended dose is 750 mg (30 ml) at once then 250 mg (10 ml) every 8 hours until the attack has passed.

For muscle joint or tendon problems and period pain: the recommended starting dose is 500 mg (20 ml), followed by 250 mg (10 ml) at 6–8 hour intervals as needed, with a maximum daily dose after the first day of 1250 mg.

Children over 5 years with rheumatoid arthritis:

The recommended daily dose is 10 mg/kg divided into two doses. Patients weighing over 50 kg may be administered the adult dosage.

body weight	daily dose	body weight	daily dose
20–24 kg	4 ml x 2	35–40 kg	7 ml x 2
25–29 kg	5 ml x 2	40–44 kg	8 ml x 2
30–34 kg	6 ml x 2	45–49 kg	9 ml x 2

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.

Important!

Shake the bottle well before each dose.

If you experience stomach complaints during the naproxen treatment, stop using this medicine and contact your doctor. See also the section “Possible side effects”.

If you take more Naproxen than you should

Contact immediately a doctor, hospital, or Poison Information Centre, if you take, or somebody else, for example a child, takes by mistake too high a dose of this medicine. Possible symptoms of overdose include nausea, vomiting, stomach pain, drowsiness, loss of consciousness, or convulsions.

Take this medicine pack with you if you go to a doctor's office or a hospital.

If you forget to take Naproxen

Take the missed dose as soon as possible. If it is almost time to take the next dose, skip the missed dose. Do not take a double dose or two doses successively.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Debilitated patients, patients with other diseases and elderly patients are more susceptible to the adverse effects. **The risk of serious adverse effects increases at high doses in long-term use and is multiplied if other anti-inflammatory analgesics are used at the same time.**

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. Signs include upset stomach, stomach pain, fever, feeling or being sick.

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.

<u>Other side effects</u>

<u>Very common</u> *(may affect more than one patient out of 10):*
- upper stomach pain, heartburn, nausea, constipation.

<u>Common</u> *(may affect less than one patient out of 10):*
- headache, tiredness, light-headedness, dizziness
- visual disturbances
- ear ringing and buzzing (tinnitus), hearing disorders
- worsening of heart failure (swellings, shortness of breath)
- inflammation of the mouth, diarrhoea, vomiting, digestion problems
- skin symptoms (e.g. itching, nettle rash, red spots, bruises), increased sweating.

<u>Uncommon</u> *(may affect less than one patient out of 100):*
- increased potassium level
- mood changes, depression, impaired ability to concentrate, sleep disorders, disorders of memory and thinking (cognitive disorders)

- palpitations
- gastrointestinal bleedings or ulcers, blood in vomit, blood in stools, bowel obstruction
- increased liver enzyme values, jaundice
- menstrual disorders.

Rare *(may affect less than one patient out of 1,000):*
- hypersensitivity reactions, intense systemic allergic reaction (anaphylaxis), sudden swelling of the neck, lips, tongue and possibly arms and legs (angioedema)
- hearing impairment
- worsening of asthma
- inflammation of the liver
- hair loss, photosensitivity, skin alterations and blistering (pseudoporphyria)
- muscle pain, muscle weakness.

Very rare *(may affect less than one patient out of 10,000):*
- anaemia, clotting problems, changes to the number of white blood cells
- hallucinations, confusion
- meningitis, worsening of Parkinson's disease, convulsions, paraesthesia (tingling or 'pins and needles'), inflammation of the optic nerve
- eye disorders
- vertigo
- inflammation of the blood vessels
- inflammation of the lungs, shortness of breath, wheezing
- swelling of salivary glands, inflammation of the pancreas
- severe skin or mucosal reactions with peeling or blistering (e.g. Stevens-Johnson's syndrome), *erythema multiforme*, exacerbation of skin diseases (e.g. *lichen planus*, *erythema nodosum*)
- blood in urine, adverse kidney effects (e.g. kidney failure and inflammation of the kidneys), increased creatinine level
- female infertility
- drowsiness, thirst, fever, fatigue or sickness.

Not known *(frequency cannot be estimated from the available data):*
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS). See also section 2.
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching.

The use of anti-inflammatory analgesics, such as Naproxen, may be associated with a small increased risk of a heart attack or stroke.

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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naproxen

This medicine does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

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 contains

- The active substance is naproxen. One millilitre contains 25 mg naproxen.
- The other ingredients are sorbitol (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), anhydrous citric acid, sodium citrate, glycerol 85%, xanthan gum, microcrystalline cellulose, sodium carboxymethyl cellulose, polysorbate 80, sucralose (E955), purified water and chocolate flavour.
- Chocolate flavour contains ethyl vanillin, vanillin, isoamyl phenylacetate, heliotropine, 2,3,5-trimethyl pyrazine, maltol, cinnamaldehyde, propylene glycol (E1520), triacetin (E1518).

What Naproxen looks like and contents of the pack

White or off-white suspension.

Pack sizes: 100 ml and 200 ml (plastic bottle) including a dosing syringe.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer
Orion Corporation
Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

Orion Corporation
Orion Pharma
Volttikatu 8
FI-70700 Kuopio
Finland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (UK) Limited, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA

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