Package leaflet: Information for the user

Naproxen 50mg/mL Oral Suspension

For children from 2 years of age and adults

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.

The name of your medicine is Naproxen 50mg/mL Oral Suspension but will be referred to as Naproxen throughout this leaflet.

What is in this leaflet

1. What Naproxen is and what it is used for

Naproxen contains a medicine called naproxen. This is a 'Non-Steroidal Anti-Inflammatory Drug' or NSAID.

Naproxen is used in adults for the symptomatic treatment of:
- pain and inflammation in:
  - rheumatoid arthritis, ankylosing spondylitis (pain and stiffness in the neck and back), acute attacks of osteoarthrosis and spondylarthrosis
  - acute gout
  - inflammatory rheumatic diseases of soft tissues
  - painful swelling or inflammation after musculoskeletal injuries
- period pain

It can also be used in children from 2 years of age and adolescents with rheumatoid arthritis.

2. What you need to know before you take Naproxen

Do not take Naproxen:
- if you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6).
- if you have a history of asthma attacks, angioedema, skin reactions or acute rhinitis after taking acetylsalicylic acid or any other NSAIDs.
- if you have blood formation disturbances.
- if you have now an ulcer or bleeding in your stomach or gut.
- if you have a history of recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (at least two different episodes of confirmed ulcers or bleeding).
- if you have previously experienced bleeding or perforation in your stomach or gut while taking NSAIDs.
- if you have severe kidney, liver or heart failure.
- if you have a brain bleed.
- if you currently have any other form of acute bleeding.
- if you are in the last three months of pregnancy (see 'Pregnancy, breast-feeding and fertility').

Warnings and precautions
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control the symptoms.

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, have ever had a stroke or think that you may be at increased risk for these conditions (e.g.: high blood pressure, diabetes, elevated cholesterol levels, or if you smoke), discuss this treatment with your doctor or pharmacist.

Talk to your doctor or pharmacist before taking Naproxen:

- if you have asthma, allergies (like hayfever) or chronic obstructive airway disease or have had swelling of the face, lips, eyes or tongue in the past.
- 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 a feeling of weakness (perhaps because of an illness) or you are an older person.
- if you have problems with your kidneys or liver.
- if you have problems with the way that your blood clots.
- if you are taking medicines such as corticosteroids, anticoagulants, selective serotonin re-uptake inhibitors (SSRIs), acetylsalicylic acid or NSAIDs including COX-2 inhibitors.
- if you have previously experienced stomach ulcer or bleeding. You will be asked to report any unusual symptoms from your stomach to your doctor.
- if you have an autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) or mixed connective tissue disease and ulcerative colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).
- if you have problems with vision or hearing.
- if you have had a major surgery shortly before starting treatment with Naproxen.
- if you have heavy menstrual bleeding.
- if you have a disorder of the biosynthesis of the red pigment that gives blood its colour (porphyria).

This medicine must be stopped immediately in case of gastrointestinal bleeding or visual disturbances or hearing impairment.

Serious skin reactions (including exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported in association with Naproxen Oral Suspension. Stop using Naproxen Oral Suspension and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
General information
Pain relief and underlying illness
If, during treatment with naproxen, you do not feel better, or if you should continue to have pain, fever, fatigue or other signs of illness, please ask your doctor for advice. This is because painkillers may mask possible warning signs of an underlying illness.

Headache from painkillers
Prolonged, high-dose use of painkillers may cause headaches that must not be treated by taking more painkillers.

Kidney damage from painkillers
Habitual use of certain painkillers for a prolonged period of time may lead to permanent kidney damage with the risk of kidney failure.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take Naproxen.
Laboratory test results
If your doctor recommends monitoring of your blood counts, blood clotting and/or liver and kidney function and/or any other tests (e.g. determination of the blood levels of certain medicines), it is essential that you have these tests performed. This applies particularly to patients with impaired liver function, heart failure, high blood pressure or kidney damage.

If you need to have an adrenal function test done, you must (temporarily) stop taking Naproxen at least 3 days before the test to avoid interference with the test result.

Children and adolescents
Naproxen is not recommended for use in children under 2 years of age because there is no adequate experience.

Naproxen is not recommended for use in any disorder other than juvenile rheumatoid arthritis in children and adolescents under 18 years of age.

Other medicines and Naproxen
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 NSAIDs including salicylates (like acetylsalicylic acid) and COX-2 inhibitors
- Aspirin/acetylsalicylic acid to prevent blood clots
- Glucocorticoids (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone
- Medicine to stop your blood clotting, like warfarin, heparin or clopidogrel
- Phenytoin (used to treat epilepsy)
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including sulphonamide antibiotics (for infections)
- Oral medicines for the treatment of diabetes like glimepiride 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 or triamterene
- A 'cardiac glycoside' (for heart problems), like digoxin
- A 'quinolone antibiotic' (for infections), like ciprofloxacin or moxifloxacin
- Certain medicines for mental health problems like lithium or selective serotonin reuptake inhibitors (SSRIs) like fluoxetine or citalopram
- Probenecid and sulphinpyrazone (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)
- 'Antacids' (neutralise excess acid in the stomach)

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

Naproxen with food, drink and alcohol
The consumption of alcoholic drinks during treatment with Naproxen increases the risk of bleeding in the gastrointestinal tract (stomach/intestine) and should therefore be avoided.

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.

Pregnancy
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.

Do not take Naproxen after childbirth because it may delay the process of the uterus shrinking back into its normal shape and size.

Breast-feeding
You should avoid taking Naproxen if you are breast-feeding since it may pass into human milk in small amounts.

Fertility
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.

Driving and using machines
Naproxen may make you tired, dizzy, have problems with your eyesight or other central nervous disturbances may occur. Talk to your doctor if any of these happen to you and do not drive or use any tools or machines.

Naproxen contains sucrose, sorbitol, sodium and methyl parahydroxybenzoate

Sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. One mL contains 300mg sucrose (sugar). This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

Sorbitol
This medicine contains 90mg sorbitol in each mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sodium
This medicine contains 9.2mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0.46% of the recommended maximum daily dietary intake of sodium for an adult.

Methyl parahydroxybenzoate
This medicinal product contains methyl parahydroxybenzoate as preservative. May cause allergic reactions (possibly delayed).

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.

Shake the bottle vigorously before use. Take Naproxen with a sufficient amount of liquid. Naproxen starts to act earlier when taken on an empty stomach. Patients with sensitive stomach are advised to take Naproxen during meals.

Naproxen – like all NSAIDs – should be taken at the lowest dose necessary for pain relief for the shortest possible period of time. This precaution helps minimise possible side effects.

The pack contains an 8mL graduated oral syringe with graduations of 0.1mL which should be used to administer this medicine.

Using the oral syringe:

- Immerse the tip of the oral syringe in the medicine.
- Whilst holding the syringe in place, gently pull the plunger up drawing the medicine to the correct mark on the syringe.
- When bubbles occur, release the medicine back into the bottle and pull up the medicine again to the correct mark on the syringe.
- Remove the syringe from the bottle.
- Place the end of the syringe in the patient's mouth and gently press the plunger down to slowly and gently release the medicine.
- After use replace the bottle cap. Wash the syringe with water. Disassemble the two parts of the syringe and allow to dry. Store out of the reach of children.

Unless otherwise prescribed by your doctor, the recommended dose is:

Adults up to 65 years of age
The recommended dose range is 10–20mL of Naproxen (500mg to 1,000mg naproxen) per day. A daily dose of 20mL of Naproxen (1,000mg naproxen) should not be exceeded.

Dosage should be individually adjusted to the clinical condition.

Symptomatic treatment of painful swelling or inflammation after musculoskeletal injuries
The usual initial dose is 10mL of Naproxen (500mg naproxen). If necessary, you can take an additional dose of 5mL (250mg naproxen) every 6 to 8 hours. The daily dose should not exceed 20mL of Naproxen (1,000mg naproxen).

Symptomatic treatment of pain and inflammation in rheumatoid arthritis, ankylosing spondylitis and acute attacks of osteoarthrosis and spondylarthrosis as well as in inflammatory rheumatic diseases of soft tissues
The daily dose is usually 10–15mL of Naproxen (500–750mg naproxen). At the start of therapy, during phases of acute inflammation or when switching from another high-dose NSAID to Naproxen, the recommended dose is 15mL of Naproxen (750mg naproxen), taken as two divided doses per day (10mL of Naproxen in the morning and 5mL in the evening, or vice versa) or as a single dose (either in the morning or in the evening).

In individual cases, your doctor can increase the daily dose to 20mL of Naproxen (1,000mg naproxen).

The maintenance dose is 10mL of Naproxen (500mg naproxen) per day, which may be taken either in two divided doses (5mL in the morning and 5mL in the evening) or as a single dose (either in the morning or in the evening).

Symptomatic treatment of pain and inflammation in acute gout
The usual initial dose is 15mL of Naproxen (750mg naproxen); thereafter, take 5mL of Naproxen (250mg naproxen) every 8 hours until the attack is over. During acute gout attacks, you may thus exceed the maximum daily dose of 20mL (1,000mg naproxen) (for a short period of time).

Symptomatic treatment of period pain
The usual initial dose is 10mL of Naproxen (500mg naproxen); thereafter, you may take 5mL of Naproxen (250mg naproxen) every 6–8 hours. A daily dose of 20mL of Naproxen (1,000mg naproxen) should not be exceeded.

Children from 2 years of age and adolescents for the treatment of rheumatoid arthritis
The recommended dose is 10mg naproxen/kg body weight per day which corresponds to a daily dose of 0.2mL of Naproxen per kilogram of body weight, administered in two divided doses (single dose 0.1mL of Naproxen (5mg naproxen) per kilogram body weight). The daily dose for adolescents should not exceed 20mL (1,000mg naproxen).

Naproxen is not recommended for use in children under 2 years of age (see section 'Warnings and precautions', subsection 'Children and adolescents').

Special patient populations
Elderly (over 65 years of age)
Careful monitoring by your doctor is necessary. In older patients it is particularly important to select the lowest effective dose of Naproxen for the shortest possible duration (see section 2 'What you need to know before you take Naproxen').

Patients with impaired liver function
Patients with impaired liver function are at risk of overdose when taking Naproxen. Therefore, the lowest dose of Naproxen that is still effective should be selected. Careful monitoring by your doctor is necessary.

Should your liver function be severely impaired, you must not take Naproxen (see section 2 'What you need to know before you take Naproxen').

Patients with impaired kidney function
Should your kidney function be impaired, your doctor may want to reduce your Naproxen dose.

Should your kidney function be severely impaired, you must not take Naproxen (see section 2 'What you need to know before you take Naproxen').

Duration of treatment
The duration of use is decided by the treating physician.

For rheumatic diseases, it may be necessary to take Naproxen over a prolonged period.

In period pain the treatment duration depends on the respective symptomology. However, the treatment with Naproxen should not exceed a few days.

If you take more Naproxen than you should
If you take more Naproxen than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

For healthcare professionals: Information on how to manage poisoning with naproxen can be found at the end of this package leaflet.

If you forget to take Naproxen
Do not take a double dose to make up for a forgotten dose. Continue taking Naproxen as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 Oral Suspension and immediately contact a doctor if you notice any of the following side effects:
Severe allergic reactions (may affect up to 1 in 10,000 people), signs include:
- Shortness of breath
- Large drop in blood pressure
- Swelling of the face or throat, difficulty swallowing
- (Itchy) skin rash, redness, small blisters

Serious skin reactions (frequency cannot be estimated from the available data), e.g.:

- 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.

Serious stomach and gut problems (may affect up to 1 in 10 people), signs include:

- Relatively severe abdominal (stomach) pain - especially if onset is sudden
- Bloody vomit or coffee grounds-like vomit
- Bloody or black stools
- Ulcers, perforations (holes) and bleeds in your stomach or gut sometimes fatal particularly in elderly

Heart attack, signs include:
- Chest pain which may spread to your neck and shoulders and down your left arm

Liver problems (may affect up to 1 in 10,000 people), signs include:
- Severe fatigue with loss of appetite, with or without yellow colouration of the skin and the whites of the eyes
- Feeling or being sick, or pale coloured stools

Impairment of sensory organs, e.g.:
- Suddenly occurring visual disturbances (may affect up to 1 in 10,000 people) or hearing impairment (may affect up to 1 in 10 people)

Aseptic meningitis (may affect up to 1 in 10,000 people), signs include:
- Severe headache - especially if onset is sudden
- Stiff neck, fever, feeling or being sick
- Confusion, sensitivity to bright light

Patients with autoimmune diseases (SLE, mixed connective tissue diseases) are at increased risk for developing meningitis.

Blood and lymphatic disorders (may affect up to 1 in 10,000 people), signs include:
- Flu-like symptoms, mouth sores, sore throat and nosebleeds

Naproxen may cause the following side effects:
Very common side effects (may affect more than 1 in 10 people):
- Feeling sick
- Being sick
- Heartburn
- Stomach pain
- Fullness
- Constipation or diarrhoea and minor blood loss in the gastrointestinal tract which, in exceptional cases, may cause anaemia

Common side effects (may affect up to 1 in 10 people):
- Bleeding of the skin and mucous membranes
- Depression
- Dream abnormalities
- Difficulty falling asleep or staying asleep (insomnia)
- Headache
- Dizziness
- Agitation
- Irritability
- Sleep disturbances
- Tiredness
- Perception disorders and cognitive dysfunction
- Ringing noises in the ears
- Vertigo (dizziness)
- Sweating
- Fluid deposits in the body (oedema), especially in patients with high blood pressure
- Thirst

Uncommon side effects (may affect up to 1 in 100 people):
- Blood count changes
- Increased counts of certain types of white blood cells (eosinophilia)
- Asthma attacks (with and without drop in blood pressure)
- Inflammation of the lungs (eosinophilic pneumonia)
- Symptoms in the lower abdomen (e.g. inflammation of the large bowel with bleeding or worsening of Crohn's disease/ulcerative colitis)
- Inflammation of the lining of the oral cavity (mouth)
- Injury to the food pipe
- Changes in liver function with transaminase elevation
- Hair loss (usually temporary)
- Inflammation of the skin caused by (sun)light (which may include blistering)
- Muscle pain
- Muscle weakness
- Acute kidney failure
- Impairment of kidney function (nephrotic syndrome)
- Inflammation of the kidney(s) (interstitial nephritis)
- Fever and chills, malaise
- Inflammation of the stomach lining
- Gas

Rare side effects (may affect up to 1 in 1,000 people):
- Blistering skin conditions (epidermolysis bullosa-like reactions)

Very rare side effects (may affect up to 1 in 10,000 people):
- Decreased red and/or white blood cell and/or blood platelet counts (aplastic or haemolytic anaemia, thrombocytopenia, leukopenia, pancytopenia, agranulocytosis)
- Seizures (fits)
- Nerve inflammation
- High blood pressure
- Acceleration of the heart rate
- Pounding heart
- Heart failure
- Inflammation of blood vessels
- Worsening of infection-related inflammation (e.g. development of necrotising fasciitis, i.e. acute inflammation and necrosis [death of tissue] of the fatty tissue beneath the skin and muscles)
- Anaphylactic or anaphylactoid systemic reactions
- Liver inflammation (hepatitis), liver damage especially after longterm therapy
- Hypersensitivity reactions such as skin rash, erythema multiforme, in isolated cases manifesting as severe cutaneous adverse reactions (including Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Kidney damage (renal papillary necrosis) (especially during long-term therapy)
- Increased uric acid level in the blood

Not known (frequency cannot be estimated from the available data):
- Increased potassium levels
- Decreased white blood cell counts (neutropenia)
- Swelling of the lens and optic nerve head
- Corneal opacity
- Inflammation of the optic nerve head
- Pins and needles or numbness of your hands and feet
- Lung oedema
- Inflammation of the pancreas (a large gland behind the stomach)
- Erythema nodosum (a skin inflammation that involves reddish painful bumps)
- Lichen planus (a non-infectious, itchy rash that can affect many areas of the body)
- Systemic lupus erythematosus (SLE, an autoimmune condition leading to an inflammatory process that can affect various parts of the body)
- Pustular reaction
- Blood in the urine (haematuria)
- Inflammation of certain parts of the kidneys (glomerulonephritis)
- Female infertility
- Oedema

Naproxen may interfere with laboratory test results; you should therefore inform all of your doctors (if applicable) that you are taking Naproxen (see section 2 'What you need to know before you take Naproxen').

Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

Side effects in children and adolescents
The frequency, type and severity of side effects in children and adolescents are similar to those in adults.

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 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

Keep out of the sight and reach of children.
Store in the original package in order to protect from light.
After first opening, this medicine is stable for 3 months. Store in the original package in order to protect from light.
Do not take the suspension after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
If the suspension becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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. Contents of the pack and other information

The active ingredient is naproxen.
Each ml of suspension contains 50mg naproxen.

The other ingredients are methyl parahydroxybenzoate (E218), potassium sorbate (E202), tragacanth (E413), sucrose, sorbitol 70% solution (E420), sodium chloride, citric acid (E330), sodium saccharin (E954), sodium cyclamate (E952) and purified water.

What Naproxen looks like and contents of the pack
Naproxen is a white to yellowish-white oral suspension.
It comes in an amber glass bottle with child-resistant screw closure and an 8mL graduated oral syringe with graduations of 0.1mL.

It is available in pack size of 100ml suspension.

Manufactured by: InfectoPharm Arzneimittel und Consilium GmbH, Von-Humboldt-Str. 1, 64646 Heppenheim, Germany.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

POM

Naproxen 50mg/mL Oral Suspension; PL 18799/4078

Leaflet date: 21.01.2025

Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

The following information is intended for healthcare professionals only:

In case of a naproxen overdose:
Symptoms of overdose
Symptoms of overdose may include CNS disturbances including headache, dizziness or lightheadedness, and epigastric pain and abdominal discomfort, indigestion, nausea, vomiting, transient change in hepatic function, hypoprothrombinaemia, renal dysfunction, metabolic acidosis, apnoea and disorientation. Naproxen can be absorbed rapidly. High and early drug concentrations in the blood should be expected. A few patients have experienced seizures, but it remained unclear whether these were caused by treatment with naproxen. Gastrointestinal bleeding may also occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactic reactions have been described after treatment with non-steroidal anti-inflammatory drugs and may also occur following overdose.

Management of overdose
Patients should be treated symptomatically. There is no specific antidote. Preventive measures to avoid further absorption (e.g. administration of activated charcoal) may be indicated in patients within four hours after ingestion or because of a large overdose. Forced diuresis, alkalinisation of urine, haemodialysis or haemoperfusion are probably unsuitable because of the high protein binding of naproxen.