

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

NAXYN® 500 mg Tablets

Composition

Each tablet contains:
Naproxen 500 mg

For information on inactive ingredients and allergens: see section 2 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

NAXYN 500 mg is intended for use with the following conditions:

- relief of signs and symptoms of rheumatic diseases, including osteoarthritis, ankylosing spondylitis, both in the treatment of acute flares and in long-term management of the disease.
- juvenile rheumatoid arthritis.
- musculoskeletal and periarticular disorders.
- relief of pain in tendinitis, bursitis, synovitis, tenosynovitis, and lumbago.
- relief of pain, swelling, tenderness, and fever in acute gouty arthritis.
- relief of symptoms of dysmenorrhea.

Therapeutic group: Nonsteroidal anti-inflammatory drugs (NSAIDs).

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to naproxen, naproxen sodium or to any of the other ingredients that this medicine contains (see section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information').
- You are sensitive (allergic) to aspirin, another medicine of the nonsteroidal anti-inflammatory drugs class (NSAIDs) or any other analgesic (such as ibuprofen or diclofenac).
- You have now or have ever had any problems with your stomach or gut (intestine), such as an ulcer or bleeding.
- You have previously experienced bleeding or perforation in your stomach while taking NSAIDs.
- You have **severe** kidney, liver or heart problems.
- You are in the last three months of pregnancy.

Special warnings regarding use of this medicine

Before using NAXYN 500 mg, tell your doctor or pharmacist if you have heart problems, have had a stroke or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol or if you are a smoker).

Before using NAXYN 500 mg, tell your doctor or pharmacist if you have any of the following conditions:

- Asthma or allergies (such as hay fever) or have had in the past swelling of the face, lips, eyes or tongue.
- A feeling of weakness (possibly because of an illness) or you are an elderly person.
- Lumps (polyps) in the nose or you sneeze a lot or have a runny, blocked, or itchy nose (rhinitis).
- Problems with the kidneys or liver.
- Blood coagulation problems.
- Problems with the blood vessels (arteries) anywhere in the body.
- Too much fat in the blood (hyperlipidemia).
- An autoimmune disease, such as systemic lupus erythematosus (SLE, causing joint pain, skin rashes and fever) and colitis or Crohn's disease (conditions causing inflammation of the bowel, abdominal pain, diarrhea, vomiting and weight loss).

If any of the above conditions apply to you, or if you are not sure, consult your doctor or pharmacist before using the medicine.

Children and adolescents

For directions for use in children and adolescents, see section 3 'How to use this medicine?'.

Tests and follow-up

While you are taking NAXYN 500 mg your doctor may ask to see you to check you are getting the right dose for you and look for any side effects. This is particularly important in elderly patients.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist. Especially if you are taking:

- Other pain killers, like aspirin, ibuprofen, diclofenac and paracetamol.
- Medicines to prevent blood clotting, like aspirin/ acetylsalicylic acid, warfarin, heparin or clopidogrel.
- A hydantoin (for epilepsy), like phenytoin.
- Sulfonamides, like hydrochlorothiazide, acetazolamide, indapamide, including sulfonamide antibiotics (for infections).
- A sulfonylurea (for diabetes), like glimepiride or glipizide.
- ACE inhibitors or any other medicines for high blood pressure like cilazapril, enalapril or propranolol.
- Angiotensin-2 receptor blockers, like candesartan, eprosartan or losartan.
- Diuretics (for high blood pressure), like furosemide.
- Cardiac glycosides (for heart problems), like digoxin.
- Steroids (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone.
- Quinolone antibiotics (for infections), like ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems like lithium or SSRIs (selective serotonin reuptake inhibitors) like fluoxetine or citalopram.
- Probenecid (for gout).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Ciclosporin or tacrolimus (for skin problems or for treatment after an organ transplant).
- Zidovudine (to treat AIDS and HIV infections).
- Mifepristone (used to terminate pregnancy or to induce labor if the baby has died).

If you are taking any of the above medicines or if you are not sure, consult your doctor or pharmacist before using the medicine.

Using this medicine and food

Swallow the tablets with a glass of water. Take the medicine with or after a meal.

Pregnancy, breastfeeding and fertility

- Do not take NAXYN 500 mg during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need to take this medicine during the first 6 months of pregnancy or while you are trying to get pregnant, use the lowest dose for the shortest time possible. If NAXYN 500 mg is taken for more than a few days from 20 weeks of pregnancy onward, it can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, consult your doctor who may recommend additional monitoring.
- Do not take NAXYN 500 mg if you are in the last three months of pregnancy, since it can harm your baby. The treatment can cause kidney and heart problems in your unborn baby, affect your and your baby's tendency to bleed, and cause labor to be later or longer than expected.
- If you are pregnant or breastfeeding, think you are pregnant or are trying to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.
- NAXYN 500 mg may make it more difficult to become pregnant. Tell your doctor if you are planning to become pregnant or if you have difficulties becoming pregnant.

Driving and using machines

NAXYN 500 mg may cause tiredness, drowsiness, dizziness, problems with your eyesight and balance, depression or difficulty sleeping. Tell your doctor if you experience any of these effects, and do not drive or use any tools or machines.

Important information about some of this medicine's ingredients

- The medicine contains lactose. If you have been told by your doctor that you have intolerance to certain sugars, consult your doctor before taking this medicine.
- The medicine contains a yellow dye called Sunset FCF (sunset yellow FCF (E 110), FD&C Yellow No. 6), which may cause allergic reactions.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

If you need a dose of 250 mg or some other dose that cannot be achieved with this product's strength, ask your doctor for an alternative product.

Your doctor will tell you how to get the dose you need.

The recommended dose is usually:

Rheumatic diseases

The recommended daily dose is 500 mg or 1000 mg once a day, in the morning or in the evening. Alternatively, you may take 250 mg or 500 mg twice a day, in the morning and in the evening, at intervals of 12 hours between doses.

Musculoskeletal and periarticular disorders

A starting dose of 500 mg, followed by 250 mg taken at intervals of 8–12 hours.

Acute gouty arthritis

A starting dose of 750 mg, followed 8 hours later by a dose of 500 mg, and then 250 mg every 8 hours until the attack has passed.

Dysmenorrhea

500 mg when period pain starts, followed by 250 mg every 6 hours until the symptoms subside, and up to a total dose of 1250 mg per day.

Note that for doses requiring a 250 mg dose, an alternative medicine should be considered, because these tablets have no score line and cannot be divided.

Juvenile rheumatoid arthritis

Children over 5 years old: The recommended daily dose is 10 mg/kg body weight each day, divided into two doses per day, given at 12-hour intervals. In cases where the calculated dose based on body weight requires a dose lower than 500 mg, an alternative treatment should be considered.

Elderly patients and patients with liver problems

If you are elderly or have a liver problem, your doctor will decide on the right dose for you. This will usually be a lower dose than the recommended dose.

Do not exceed the recommended dose.

Manner of use:

- Swallow the tablets with a glass of water.
- Take the medicine with or after a meal.
- There is no information regarding crushing and chewing. Do not split the tablet since there is no score line in the tablet.

Medicines such as NAXYN may be associated with a small increase in the risk of heart attack (myocardial infarction) or stroke. The risk increases with higher doses and prolonged treatment. **Do not exceed (take more than) the recommended dose or duration of treatment.** Consult your doctor if you are not sure.

You should make sure that you drink enough during the treatment with NAXYN 500 mg. This is particularly important for patients who have kidney problems.

During the treatment with NAXYN 500 mg your doctor may want to see you to check that you are receiving the right dose for you and check for any side effects.

This is particularly important for elderly patients.

If you have accidentally taken a higher dosage, if you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Follow the treatment as recommended by your doctor.

If you forgot to take this medicine

- If you forgot to take a dose, skip the forgotten dose and take the next dose at the usual time.
- Do not take a double dose to compensate for the forgotten dose.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using NAXYN 500 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Medicines such as NAXYN 500 mg may be associated with a small increase in the risk of heart attack (myocardial infarction) or stroke.

Stop taking this medicine and contact a doctor immediately if any of the following effects appear. You may need immediate medical treatment:

Serious stomach or bowel problems, signs include:

- Bleeding from the stomach, seen as vomit with blood in it, or with bits that look like coffee grounds.
- Bleeding from the anus, seen as black sticky stool or bloody diarrhea.
- Ulcers or holes (perforation) forming in the stomach or bowel. Signs of this include abdominal discomfort, abdominal pain, fever, nausea or vomiting.
- Pancreas problems. Signs include severe abdominal pain spreading to the back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhea, vomiting, and weight loss.

Allergic reactions, signs include:

- Sudden swelling of the throat, face, hands or feet.
- Difficulty breathing, tightness in the chest.
- Skin rashes, blisters or itching.
- Widespread rash
- High fever.

Severe skin rashes, signs include:

- A severe rash with blisters or peeling of the skin and possibly blisters in the mouth, throat or eyes. Fever, headache, cough, and body aches may appear at the same time.
- Blistering of skin following exposure to sunlight (porphyria cutanea tarda) seen mainly on arms, face, and hands.
- 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), and itching.

Liver problems, signs include:

- Yellowing of the skin or the whites of your eyes (jaundice).
- Feeling tired, loss of appetite, nausea or vomiting and pale colored stools (hepatitis), and problems shown in blood tests (including hepatitis).
- Liver enzyme elevations.

Heart attack, signs include:

- Chest pain which may spread to the neck, shoulders and down the left arm.

Stroke, signs include:

- Muscle weakness and numbness. These sensations may appear only on one side of the body.
- A sudden change in the sense of smell, taste, hearing or vision, confusion.

Meningitis, signs include:

- Fever, nausea or vomiting, a stiff neck, headache, sensitivity to bright light and confusion (especially in patients with autoimmune diseases such as systemic lupus erythematosus).

Other side effects:

Stomach and gut

- Heartburn, indigestion, abdominal pain, nausea or vomiting, constipation, diarrhea, gas.

Blood

- Blood problems, like anemia or changes in the numbers of white blood cells.
- Blood abnormalities (eosinophilia).

Mental illnesses

- Difficulty sleeping or changes in the pattern of dreaming.
- Depression.
- Confusion or hallucinations (seeing and possibly hearing things that are not real).

Nervous system

- Headache.
- Fits or seizures, feeling dizzy or sleepy.
- Sensation of pins and needles or numbness of your hands and feet.
- Difficulties with 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 balance problems.

Heart and circulation

- Swelling of the hands, feet or legs (edema), which may be accompanied by chest pain, tiredness, and shortness of breath (heart failure).
- Feeling that your heart is pounding (palpitations). Slow heartbeat or high blood pressure.
- Problems with the way the blood is pumped through the body or damage to the blood vessels. Signs may include tiredness, shortness of breath, feeling faint, and general pain.

Chest

- Difficulties 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 the body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun, or hair loss.

Urinary

- Blood in the urine or kidney problems.

Other side effects

- Thirst, fever, feeling tired or generally unwell.
- A sore mouth or mouth ulcers.
- Muscle pain or weakness.
- In women – problems getting pregnant.
- Systemic lupus erythematosus (SLE). Signs include fever, rash, kidney problems and joint pain.
- Enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms, which is also known as DRESS).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C.
- Do not dispose of any medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, starch, povidone, magnesium stearate, hypromellose, polyethylene glycol 400, polyethylene glycol 6000, D&C yellow No. 10, FD&C yellow No. 6 (Sunset yellow FCF (E 110)).

What the medicine looks like and contents of the package:

Round, yellow film-coated tablets.

Each pack contains 30 tablets in a blister pack.

Name and address of the manufacturer and license holder:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in May 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
055.98.20619