

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?

For relief of signs and symptoms of rheumatic diseases, arthritis, joint disorders, tendon inflammation, musculoskeletal disorders and relief of back pain and menstrual pain.

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 in this medicine, 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 about using this medicine

If you have heart problems, have had in the past a stroke or think that you might be at risk of such conditions (for example, if you have high blood pressure, diabetes, high cholesterol levels or if you are a smoker), you should consult your doctor or pharmacist regarding the treatment.

Before using NAXYN 500 mg, tell your doctor if you have:

- Asthma or allergies (such as allergic rhinitis) 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 lipids 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.

Drug interactions

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

- Other analgesics, 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.
 - Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and sulfonamide antibiotics (for infections).
 - A sulfonylurea (for diabetes), like glibenclamide or glipizide.
 - ACE inhibitors or other medicines for hypertension 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).
 - Cyclosporin or tacrolimus (for skin problems or after an organ transplant).
 - Zidovudine (to treat AIDS and HIV infections).
 - Mifepristone (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 if you are in the last three months of pregnancy, since it can harm your baby.
- This medicine has the potential side effect of kidney damage in an unborn baby and low amniotic fluid as of Week 20 of pregnancy. It is recommended to refrain from using NSAIDs starting in Week 20 of pregnancy and to consult a healthcare professional if necessary.
- If you are pregnant or breastfeeding, think you are pregnant or are planning 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. You should 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 vision 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 a sugar called 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 dye called FD&C Yellow No. 6 (Sunset yellow FCF (E 110)), 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.

This medicine is usually not intended for children below the age of 12 years.

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 the medicine, immediately

contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Adhere to the treatment as recommended by the doctor.

If you forgot to take this medicine

- If you forgot to take a dose, skip the forgotten dose and take the next dose as you usually do.
- Do not take a double dose to compensate for the forgotten dose.

Do not take medicines in the dark! Check the label and the dose each time you take a 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

Like with all medicines, using NAXYN 500 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not suffer from any of them.

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

Important side effects to look out for:

Stop taking this medicine and consult your doctor immediately if any of the following effects appears. You may need urgent medical treatment:

Serious stomach or bowel problems, signs include:

- Bleeding from the stomach, seen as vomit with blood in it, or bits that look like coffee grounds.
- Bleeding from the anus, seen as black sticky stool or bloody diarrhea.
- Ulcers or holes forming in the stomach or bowel. Signs include abdominal tenderness, 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, manifested 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.

Severe skin rashes, signs include:

- A severe rash that develops quickly, 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 due to exposure to sunlight (porphyria cutanea tarda) seen mainly on arms, face and hands.

Liver problems, signs include:

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

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 people with autoimmune diseases such as systemic lupus erythematosus).

If you notice any of the serious side effects listed above, stop taking NAXYN 500 mg and consult your doctor immediately.

Other possible side effects:

Stomach and bowels

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

Blood

- Blood problems, like anemia or changes in the number of white blood cells.

Mental illnesses

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

Nervous system

- Headache.
- Fits or seizures, feeling dizzy or sleepy.
- Sensation of pricking or numbness of your hands and feet.
- Difficulties with memory or concentration.

Eyes and ears

- Changes to your sight, 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), may be accompanied by chest pain, tiredness, and shortness of breath (heart failure).
- Feeling of your heart pounding (palpitations). Slow heart beat or high blood pressure.
- Problems with the way the heart pumps blood around 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

- Thirst, fever, feeling tired or generally unwell.
- A sore mouth or mouth ulcers.
- Muscle pain or weakness.
- Problems for women in getting pregnant.
- 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, kidney problems and joint pain.

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 clicking on the link "Reporting side effects following drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, 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) that 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 throw 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. 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 pack:

Round, yellow film-coated tablets.
The tablets are packed in blisters. Each pack contains 30 tablets.

Manufacturer's name and address:

Teva Pharmaceutical Industries Ltd., POB 3190, Petach Tikva.

The leaflet was revised in June 2021 according to MoH guidelines.

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