

Naprocen

Tablets

Composition

Each tablet contains:
naproxen sodium 275 mg

For information about inactive ingredients and allergens see section 2 under '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.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult the pharmacist if you need more information. Consult your doctor if your fever lasts longer than 3 days or the pain persists for longer than 10 days.

1. What is this medicine intended for?

This medicine is intended to relieve mild and moderate pain such as toothache, backache and menstrual pain, reduce fever, treat rheumatic inflammations, tendinitis and musculoskeletal inflammations.

Therapeutic group: A pain reliever that belongs to the class of non steroidal anti inflammatory drugs (NSAIDs).

2. Before using this medicine

Do not use this medicine:

If you are hypersensitive or allergic:

- To naproxen, naproxen sodium or to any of the other ingredients in this medicine (see a list of the ingredients in section 6).
- To aspirin, any other pain reliever or other NSAIDs (such as ibuprofen or diclofenac).

Do not take this medicine if:

- You have now or have ever had any problems with your stomach or gut like an ulcer or bleeding.
- You have previously experienced bleeding or an ulcer in your digestive system while taking NSAIDs.
- You have severe problems with your kidneys, liver or heart.
- You are in the last three months of pregnancy.

Special warnings about using this medicine

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

Consult your doctor or pharmacist before starting treatment with Naprocen if you have any of the following:

- Asthma, allergies (for example hay fever) or you have had swelling of the face, lips, eyes or tongue in the past.
- Weakness (perhaps because of an illness) or you are an older person.
- Polyps in your nose or you sneeze a lot or have a runny, stuffy, or itchy nose (rhinitis).

- Problems with your kidneys or liver.
- Problems with the way that your blood clots.
- Problems with the blood vessels (arteries).
- Too much fat in your blood (hyperlipidemia).
- Autoimmune diseases such as systemic lupus erythematosus (causes joint pain, skin rashes, and fever), inflammation of the large intestine (colitis) or Crohn's disease (causing inflammation of the bowel, bowel pain, diarrhea, vomiting and weight loss).

Children and adolescents

This medicine is not intended for children under 12 years old.

Tests and follow-up

Your doctor will want to see you while you are taking Naprocen to make sure that the dose is right for you and to see whether any side effects have appeared. This is particularly important if you are older person.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Pain killers like aspirin, ibuprofen, diclofenac, paracetamol.
- Anticoagulants, like aspirin, warfarin, heparin or clopidogrel.
- A hydantoin (for epilepsy), like phenytoin.
- Sulfonamides, like hydrochlorothiazide, acetazolamide, indapamide and sulfonamide antibiotics (for infections).
- A sulfonylurea (for diabetes), like glimepiride or glipizide.
- ACE inhibitors or any other medicine for high blood pressure like cilazapril, enalapril or propranolol.
- Angiotensin-II receptor antagonists, like candesartan, eprosartan or losartan.
- Diuretics (for high blood pressure), like furosemide.
- Cardiac glycosides (for treatment of 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 disorders, like lithium, or SSRIs like fluoxetine or citalopram.
- Probenecid (for gout).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Cyclosporine or tacrolimus (for skin problems or after an organ transplant).
- Zidovudine (for treatment of AIDS and HIV).
- Mifepristone (used to end pregnancy or to bring on labor if the unborn baby has died).

Using this medicine and food

Take Naprocen with food or immediately after a meal.

Pregnancy, breastfeeding, and fertility

- This medicine has the potential side effect of kidney damage to the unborn baby and low amniotic fluid as of Week 20 of the pregnancy. It is recommended that you avoid use of NSAIDs as of Week 20 of pregnancy and consult with a healthcare professional if necessary.
- Do not take this medicine if you are in the last three months of pregnancy (last trimester), as there is a risk of harm to your unborn baby.
- If you are pregnant or breastfeeding, think you may be pregnant or are trying to become pregnant, consult your doctor or pharmacist before using this medicine.
- Naprocen may make it difficult to become pregnant. Tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Using this medicine can make you tired, drowsy, dizzy, have problems with your eyesight and balance, feel depressed and have difficulty sleeping. So be cautious about driving, operating dangerous machines, and any other activity that requires alertness. Caution adolescents over 12 years old against riding a bicycle, playing near a road, and similar activities.

Important information about some of this medicine's ingredients

- Each tablet contains about 25 mg sodium (the main ingredient in table salt). This amount is about equivalent to 1.25% of the adult recommended maximum daily intake of salt. Patients who need to limit their sodium intake should take this into account.
- This medicine contains the yellow coloring agent FD&C which may cause an allergic reaction.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Adults and children over 12 years old: one tablet every 12 hours, as needed, or a starting dose of 2 tablets in 24 hours. Do not exceed a dose of 2 tablets in 24 hours.

Older people over 65 years old: up to 1.5 tablets in 24 hours.

Do not exceed the recommended dose.

Stop taking this medicine and consult your doctor if your fever lasts longer than 3 days or pain persists for longer than 10 days.

There may be a connection between taking medicines like Naprocsen and a slight increase in the risk of heart attack or stroke. This risk evidently increases with longer use and higher doses. Therefore, **do not exceed the recommended dose or deviate from the recommended duration of treatment.**

How to use this medicine

You may split the tablets on the break line. There is no information about crushing/chewing. Swallow the tablets with a glass of water.

Take this medicine with or after a meal.

Make sure that you have enough to drink when using this medicine, particularly if you have kidney problems.

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.

If you forget to take this medicine at the required time, skip the missed dose and take the next dose on time. Do not take a double dose to make up for a missed dose.

Do not take medicines in the dark! Check the label and dose every 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

Like with all medicines, using Naprocsen may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and tell a doctor straight away if any of the following side effects appear. You may need immediate medical treatment:

Serious stomach or gut problems

- Bleeding from the stomach, which may be seen as vomit that has blood in it or bits that look like coffee grounds.
- Bleeding from your anus, which may be seen as black sticky stools or bloody diarrhea.
- Ulcers and holes in your stomach or gut. Signs of this can be upset stomach, stomach pain, fever, nausea or vomiting.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of colitis or Crohn's disease, seen as pain, diarrhea, vomiting, and weight loss.

Allergic reactions

- May be seen as sudden swelling of your face, throat, hands or feet.
- Difficulty breathing, tightness in your chest.
- Skin reactions: skin rashes, itching, and blisters.

Severe skin rashes

- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headaches, cough and general pain may happen at the same time.
- Blistering of skin when exposed to sunlight mainly appearing on the arms, face and hands.

Liver problems

- Yellowing of your skin or eyes (jaundice).
- Feeling tired, loss of appetite, nausea or vomiting, pale colored stools (hepatitis), blood test results indicating liver problems (including hepatitis).

Heart attack

- Chest pain that spreads to your neck and shoulders and down your left arm.

Stroke

- Muscle weakness and numbness. You may only feel this on one side of your body.
- Sudden changes in your sense of smell, taste, hearing, or vision, confusion.

Meningitis

- Fever, nausea or vomiting, a stiff neck, headaches, sensitivity to light and confusion (more common in patients with autoimmune diseases such as lupus).

Additional side effects

Stomach and gut

- Heartburn, indigestion, stomachache, nausea, vomiting, constipation, diarrhea, flatulence.

Blood

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

Mental illness

- Difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Confusion and hallucinations.

Nervous system

- Headaches.
- Seizures, dizziness, drowsiness.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your 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 problems with your balance.

Heart and circulation

- Swelling of your hands, feet or legs (edema), this may appear together with chest pain, tiredness, shortness of breath (heart failure).
- A fluttering feeling in your heart (palpitations), slower heart beat, high blood pressure.

- Problems with the blood flow around the body or damage to your blood vessels. Signs of this may include tiredness, shortness of breath, feeling faint, general pain.

Chest

- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Pneumonia or swelling of your lungs.

Skin and hair

- Skin rash, including redness, itchy rash (hives), pimples and blisters on your body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun, hair loss.

Urinary system

- Blood in your urine or kidney problems.

Other side effects

- Thirst, fever, feeling tired or generally unwell.
- A sore mouth or mouth ulcers.
- Muscle pain or weakness.
- Difficulty getting pregnant.
- Systemic lupus erythematosus: signs include fever, rash, problems with your kidneys, 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 of side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' 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>

Additionally, you can report by e-mail to: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store in a cool and dry place, below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains: microcrystalline cellulose, povidone, magnesium stearate, methocel E5 (HPMC), titanium dioxide, polyethylene glycol 400, FD&C yellow no.6 aluminum lake.

Each tablet contains about 25 mg sodium.

What the medicine looks like and contents of the pack:

Packs contain 20 tablets in a blister pack. Oblong, orange, film-coated tablet with a break line on one side.

Name and address of manufacturer and registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in March 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 140.34.31895.00.