

This medicine is dispensed without a doctor's prescription

NAROCIN®

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 to moderate pain such as toothache, backache and menstrual pain, reduce fever, treat rheumatic inflammations, treat tendonitis 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 any of this medicine's other ingredients (see a list of the ingredients in section 6).
- Aspirin, any other pain reliever or other NSAIDs or (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 (intestine) 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 regarding use of this medicine
Before using Narocin, 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 or high cholesterol or are a smoker).

Consult your doctor or pharmacist before taking Narocin if you have any of the following:

- Asthma or allergies (like hayfever) 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, blocked, 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 (hyperlipidaemia).
- An autoimmune condition, 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).

Use in children

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 Narocin to make sure that the dose is right for you and to see whether you are getting any side effects. This is particularly important if you are an older person.

Interactions with other medicines

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

- Pain killers like aspirin, ibuprofen, diclofenac, paracetamol.
- Blood-thinning medicines, like aspirin, warfarin, heparin, or clopidogrel.
- A hydantoin (for epilepsy), like phenytoin.
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including 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 heart problems), like digoxin.
- Steroids (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone.
- Quinolone antibiotic (for infections), like ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems 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 (used to treat AIDS and HIV infections).
- Mifepristone (used to end pregnancy or to bring on labor if the unborn baby has died).

Using this medicine and food

Take Narocin with food or immediately after a meal.

Pregnancy, breastfeeding, and fertility

- Do not take Narocin during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you have to take Narocin during the first 6 months of pregnancy or while you are trying to get pregnant, use the lowest dose for the shortest time possible. From 20 weeks of pregnancy onward, if taken for more than a few days, Narocin can cause renal impairment in the unborn baby, that may lead to low levels of amniotic fluid or narrowing of a blood vessel in the heart of the baby (ductus arteriosus). If you need treatment for longer than a few days, consult your doctor.
- Do not use Narocin if you are in the last three months of pregnancy (last trimester), as there is a risk of harm to your unborn baby. The treatment may harm the kidneys and heart of your unborn baby, and may affect your and your unborn baby's tendency to bleed and cause labor to be later or longer than expected.
- If you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Narocin may make it more 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 or have difficulty sleeping. Consult your doctor if you experience these effects and do not drive or use any tools or machines.

Important information about some of this medicine's ingredients

- Narocin contains lactose. If you have been told by your doctor that you have an intolerance (sensitivity) to certain sugars consult your doctor before taking the medicine.
- Each tablet contains about 24 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 coloring agent Sunset Yellow FCF 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 1½ 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 Narocin and a slight increase in the risk of heart attack or stroke. This risk increases with longer use and higher doses. **Do not exceed the recommended dose or the recommended duration of treatment.**

How to use this medicine

Do not chew or crush! You may split the tablets on the breakline.

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 you are taking 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 forgot to take this medicine** at the scheduled time, skip the missed dose and take the next dose at its usual 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

As with any medicine, using Narocin 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 happen. You may need immediate medical treatment:

Serious stomach or gut problems

- Bleeding from the stomach, seen as vomit which has blood in it or bits that look like coffee grounds.
- Bleeding from your anus, seen as passing 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 ulcerative 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 rashes, itching, and blisters.
- Widespread rash.
- High body temperature.

Severe skin rashes

- A severe rash with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, 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.
- A distinctive, allergic skin 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

- 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).
- Liver enzyme elevations.

Heart attack

- Chest pain which may spread 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, headache, sensitivity to light and confusion (more common in people with autoimmune conditions such as systemic lupus erythematosus).

Additional side effects

Stomach and gut

- Heartburn, indigestion, stomach ache, nausea, vomiting, constipation, diarrhea, flatulence.

Blood

- Blood problems, like anemia or changes to the numbers of white blood cells.

- Blood abnormalities (eosinophilia).

Mental illness

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Confusion and hallucinations (seeing and hearing things which do not exist).

Nervous system

- Headache.
- 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 pains, tiredness, shortness of breath (cardiac failure).
- A fluttering feeling in your heart (palpitations), slower heart beat or high blood pressure.
- Problems with the way your heart pumps blood 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 rashes 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.
- 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

You can report side effects 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 a 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 medicine 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, the medicine also contains: Microcrystalline cellulose, lactose monohydrate, purified water, magnesium stearate, hydroxypropyl methylcellulose, Sunset Yellow FCF aluminium lake (E110), macrogol, titanium dioxide.

What the medicine looks like and contents of the package: Round tablet with orange coating and a breakline on one side. Packs contain 10 or 20 tablets in blister packs.

Name and address of manufacturer and license holder: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 065.82.22014