

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Noxicam 8 mg film-coated tablets

Each Noxicam tablet contains:

Lornoxicam 8 mg

For inactive ingredients and allergens in the preparation see section 6 "Additional information" and the "Important information about some of the ingredients of the medicine" section.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine.

If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. The medicine is not intended for children under the age of 18 unless prescribed by your doctor.

1. What is the medicine intended for?

Noxicam is used for short-term treatment of mild to moderate pain (e.g., after dental surgery), back pain, osteoarthritis and rheumatoid arthritis.

Therapeutic class: non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional components the medicine contains
- You are sensitive to other non-steroidal medicines for pain and inflammation, including aspirin
- You suffer from thrombocytopenia (lack of blood platelets that increases the risk of bleeding or bruising)
- You have severe heart failure

- You suffer from gastrointestinal bleeding, injury to the blood vessels and bleeding in the brain, or other bleeding disorders
- You have a history of bleeding or perforation in the gastrointestinal system in connection with prior treatment with non-steroidal medicines for pain and inflammation
- You currently have a stomach ulcer or a history of recurrent stomach ulcers
- You have severe liver impairment
- You have severe kidney impairment
- You are in the last trimester of pregnancy

Special warnings regarding the use of the medicine

Consult the doctor or pharmacist before taking the medicine. This is especially important if you suffer from:

- Decreased kidney function
- A history of high blood pressure and/or heart failure
- Ulcerative colitis or Crohn's disease
- A history of bleeding tendencies
- A history of asthma
- Systemic lupus erythematosus

The doctor may frequently refer you to lab tests, if:

- You suffer from blood coagulation problems
- You suffer from impaired liver function
- You are elderly
- You are taking Noxicam for more than 3 months

You should inform the doctor if you are being treated with heparin or tacrolimus while taking Noxicam.

- If you notice unusual symptoms in the abdomen such as abdominal bleeding, skin reactions such as skin rash, damage to the internal mucosa of the nose, mouth, eyelids, ears, genitals or anus or other signs of hypersensitivity, **stop taking the medicine and refer to a doctor immediately.**
- Medicines such as Noxicam may slightly increase the risk of **heart attack or stroke.** The risk increases as the dosage and duration

of treatment increase. **Do not exceed the recommended dose and duration of treatment.**

Before treatment with Noxicam, tell the doctor or pharmacist if:

- You have heart diseases
- You experienced a stroke in the past
- You think you have an increased risk of developing these conditions (e.g., you suffer from hypertension, diabetes, high levels of blood cholesterol or you smoke)

Avoid using Noxicam if you have chickenpox.

Drug interactions

Noxicam can affect the way other medicines work. If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Cimetidine – for treatment of heartburn or stomach ulcer
- Anticoagulants such as heparin or phenprocoumon
- Corticosteroids
- Methotrexate – for treatment of cancer or immune system diseases
- Lithium
- Medicines that suppress the immune system such as cyclosporine and tacrolimus
- Heart disease and hypertension medicines such as digoxin, ACE inhibitors, beta blockers
- Diuretics
- Quinolone antibiotics (for example levofloxacin, ofloxacin)
- Medicines that inhibit platelet aggregation (such as clopidogrel) – used for the prevention of heart attacks and strokes
- SSRI antidepressants
- Medicines from the sulfonylurea group (such as glibenclamide) – used for the treatment of diabetes
- Medicines that inhibit or induce the enzyme CYP2C9 (such as the antibiotic rifampicin or the antifungal medicine fluconazole), as these may affect the way your body breaks down Noxicam

- Angiotensin II receptor blockers – for treatment of hypertension, kidney damage due to diabetes and heart failure
- Pemetrexed – for treatment of certain types of lung cancer

Avoid using Noxicam if you are taking other non-steroidal anti-inflammatory drugs (NSAIDs) such as **aspirin, ibuprofen or COX-2 inhibitors.**

Use of the medicine and food

The preparation is intended to be taken orally. The preparation should be taken before a meal with a sufficient amount of liquid.

Taking the preparation with food is not recommended since the food may reduce its effectiveness.

Fertility, pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult with the doctor or pharmacist before taking the medicine.

- Fertility

Using Noxicam may impair fertility, and is therefore not recommended for women planning to become pregnant.

Women who have difficulty becoming pregnant or who are undergoing tests to diagnose fertility problems should consult a doctor and consider stopping treatment with Noxicam.

- Pregnancy

Do not use Noxicam in the last three months of pregnancy, as using the medicine may harm your fetus or cause problems during labor. The preparation may cause kidney and heart problems in your fetus, affect your and your fetus's bleeding tendency, and cause a delay in the start of contractions or make the labor last longer than expected.

Do not use Noxicam during the first 6 months of pregnancy unless it is necessary and approved by your doctor.

If it is necessary to use the medicine during this period or while you are trying to become pregnant, use the lowest dosage possible and for as short a time as possible.

If you are using Noxicam for more than a few days

after the 20th week of pregnancy, the medicine may cause kidney problems in your fetus, which may lead to a reduced amount of amniotic fluid surrounding the fetus (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in your fetus's heart. If treatment for more than a few days is necessary, your doctor may recommend extra monitoring.

- Breastfeeding

If you are breastfeeding, treatment with Noxicam is not recommended, unless explicitly instructed by the doctor.

Driving and operating machinery

Noxicam has no or almost no effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine

Noxicam contains lactose monohydrate. If you suffer from intolerance to certain sugars, you should consult the doctor before using the medicine.

3. How should you use the medicine?

Use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is:

For treatment of pain

8-16 mg daily divided into 2-3 doses. The daily dosage should not exceed 16 mg.

For treatment of osteoarthritis and rheumatoid arthritis

An initial daily dose of 12 mg divided into 2-3 doses. Afterwards, a maintenance dose that does not exceed 16 mg per day.

For treatment of osteoarthritis and rheumatoid arthritis

A maximum daily dosage of 12 mg divided into 2-3 doses.

Do not exceed the recommended dose. Swallow the medicine with a sufficient amount of liquid.

Do not take Noxicam with a meal, since taking it with food may reduce the effectiveness of the medicine.

The tablet can be halved.

To facilitate swallowing, the tablet can be crushed for immediate use.

Using Noxicam is not recommended in children and adolescents under the age of 18 due to the lack of sufficient data.

If you accidentally took a higher dosage

If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

In case of an overdose, the expected side effects are: nausea, vomiting, effects related to the central nervous system (such as dizziness and blurred vision). Serious symptoms such as impaired movement coordination (including coma and convulsions), liver and kidney injury, as well as coagulation disorders may occur.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Noxicam may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not experience any of them.

- Medicines such as Noxicam may slightly increase the risk of **heart attack or stroke.**
- If you notice unusual symptoms in the abdomen

such as abdominal bleeding, skin reactions such as skin rash, damage to the internal mucosa of the nose, mouth, eyelids, ears, genitals or anus or other signs of hypersensitivity, **stop taking the medicine and refer to a doctor immediately.**

If you notice the following side effects, **stop using Noxicam and refer to the doctor or to an emergency room immediately:**

- Shortness of breath, chest pain, swelling of the ankles or worsening of the following symptoms:
 - Acute or persistent abdominal pain or black stool
 - Yellowing of the skin and the eyes (jaundice) – these are signs of a liver problem
 - An allergic reaction manifested by skin problems such as ulcers or blisters, swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
 - Fever, blistering rash or inflammation, especially on the hands, legs or around the mouth (Stevens-Johnson syndrome)
 - In isolated cases, serious skin infections caused by chickenpox

Additional side effects:

Common side effects – effects that occur in 1-10 users out of 100:

- Mild and temporary headaches and dizziness
- Nausea, abdominal pain, indigestion, diarrhea and vomiting

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Weight loss (loss of appetite), insomnia, depression
- Conjunctivitis
- Vertigo, ringing in the ears (tinnitus)
- Heart failure, racing heartbeat, irregular heart rate, flushing
- Constipation, flatulence, belching, dry mouth, gastritis, stomach or duodenal ulcer, upper abdominal pain, mouth ulcers
- Increased liver function values (determined by blood tests), general weakness
- Rash, itching, increased sweating, skin rash with redness, painful allergy with swelling of the

skin and mucous membranes, especially in the face (angioedema), hives (urticaria), edema, allergic rhinitis

- Hair loss
- Joint pain

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Sore throat
- Anemia, reduced blood count (lack of platelets and white blood cells), feeling weak
- Hypersensitivity including allergic reaction and pseudoallergic reaction (usually accompanied by a drop in blood pressure, dizziness, nausea and sometimes shortness of breath)
- Confusion, nervousness, agitation, drowsiness, abnormal sensations, tremor, taste disturbances, migraine, visual disturbances
- High blood pressure, hot flashes
- Bleeding, subcutaneous hematomas, prolonged bleeding time
- Shortness of breath, cough, bronchospasm
- Perforated stomach ulcer, vomiting blood, gastrointestinal bleeding, black stool
- Inflammation of the oral mucosa, inflammation of the esophagus, reflux (backflow of gastric fluid), difficulty swallowing, ulcers of the oral mucosa (aphthous ulcers), inflammation of the tongue

- Impaired liver function
- Skin symptoms such as eczema, rash
- Bone pain, muscle pain, muscle cramps
- Urinating disorders such as increased need to pass urine during the night or increased levels of urea and creatinine in the blood

Very rare side effects – effects that occur in 1-10 users out of 100,000:

- Liver damage, hepatitis (inflammation of the liver), jaundice, problems in the biliary tract
- Sores, edema, serious skin diseases (Stevens-Johnson syndrome, toxic epidermal necrolysis – a skin reaction caused by the use of medicines)
- Meningitis not caused by an infection
- Side effects of all medicines from the group of non-steroidal anti-inflammatory drugs (NSAIDs), such as:

- A decrease in the amount of white blood cells (called neutrophil granulocytes)
- A severe decrease in the amount of white blood cells (which increases the susceptibility to infections, fever)
- Anemia due to blood-forming bone marrow depletion (accompanied by a severe drop in all blood cells, which can lead to weakness and increased susceptibility to infections and hematomas)
- Anemia due to the breakdown of red blood cells (can lead to a pale-yellowish complexion, weakness and shortness of breath)
- Kidney injury

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your doctor. Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor
- Do not use the medicine after the expiry date (exp. date) appearing on the package
- The expiry date refers to the last day of that month

Storage conditions: no special storage conditions are required. It is recommended to store at room temperature.

6. Additional information
In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, Microcrystalline cellulose (MCC) PH 101, Croscarmellose sodium, Povidone K-25, Magnesium stearate, OPADRY OY-S-28917 Ready to use coating blend (Hypromellose 2910, Titanium Dioxide, Macrogol 8000), Iron yellow oxide, Macrogol 6000 (PEG)

What does the medicine look like and what are the contents of the package?

Noxicam is an off-white to yellow, round convex film-coated tablet, with a deep score line on one side and a shallow score line on the other side. Package sizes: 2, 7, 10, 14, 20 or 30 film-coated tablets.

Not all package sizes may be marketed.
Name and address of the manufacturer and license holder: CTS Chemical Industries Ltd., 3 Hakidma, Kiryat Malachi.

This leaflet was revised in 05/2025
Registration number of the medicine in the national drug registry of the Ministry of Health: 178-04-36865-99

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