## Patient Leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is dispensed with a doctor's prescription only

| **Etopan** | **Etopan** | **Etopan** | **Etopan** |
| --- | --- | --- | --- |
| **500** | **400** | **300** | **200** |
| Tablets | Tablets | Capsules | Capsules |
| Each tablet contains: | Each tablet contains: | Each capsule contains: | **Active ingredient**  Each capsule contains: |
| 500 mg etodolac | 400 mg etodolac | 300 mg etodolac | 200 mg etodolac |
| (etodolac 500 mg) | (etodolac 400 mg) | (etodolac 300 mg) | (etodolac 200 mg) |

Inactive ingredients and allergens: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

**Read this entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

# 1. What is the medicine intended for?

For the treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis. For the treatment of pain.

## Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

# 2. Before using the medicine

# Do not use the medicine if:

| * You are sensitive (allergic) to the active ingredient (etodolac) or to any of the other ingredients the medicine contains (see section 6). * You suffer from **severe heart failure**. * You have an ulcer (peptic ulcer, a small lesion or hole in the stomach or duodenum) or bleeding in the stomach, or have had two or more episodes of ulcers, bleeding or perforation of the stomach. * You have ever had an **allergic reaction or asthmatic reaction** (wheezing, itching or skin rash) after taking aspirin, Etopan or another non-steroidal anti-inflammatory drug. * You suffer from severe liver failure and severe kidney failure. * **You are in the last trimester of pregnancy**. * You have previously had stomach or intestinal bleeding as a result of taking a non-steroidal anti-inflammatory drug. |
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## Special warnings regarding the use of the medicine

## Before treatment with Etopan, tell the doctor if:

* You have kidney, heart or liver disease, or you suffer from a blood disorder, especially if you are also taking diuretics. The dose should be as low as possible and you should have regular check-ups.
* You are already on long-term therapy with a medicine other than Etopan, since the doctor will want to arrange regular check-ups, especially if you are elderly.
* You suffer from fluid retention (swelling of the legs, ankles or feet).
* You suffer from high blood pressure or heart failure.
* You suffer or have suffered in the past from asthma or breathing difficulties.
* You have heart problems, have had a stroke in the past or you think you may be at risk for these conditions (for example if you have high blood pressure, diabetes, high cholesterol or you are a smoker).

Medicines like Etopan may slightly increase the risk of heart attack or stroke. The risk is higher at high doses and with prolonged treatment. Do not exceed the recommended dose or duration of treatment.

**Serious gastrointestinal side effects** such as bleeding, ulceration and perforation can occur at any time during treatment with or without warning symptoms in patients treated with non-steroidal anti-inflammatory drugs. If you have any sign of gastrointestinal bleeding, **stop taking Etopan immediately**.

If you are having a blood or urine test, inform the doctor that you are taking Etopan as this medicine can affect the results.

## Children and adolescents

## Etopan is not recommended for use in children.

## Drug interactions

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

* Antithrombotic drugs such as warfarin (blood thinner) and aspirin (prevention of blood platelet clumping)
* Cyclosporine or tacrolimus (used after organ transplants)
* Digoxin - for treating heart problems
* Lithium - for treating mental illnesses
* Methotrexate - for treating conditions such as psoriasis or rheumatoid arthritis
* Corticosteroids (such as prednisolone)
* Quinolone antibiotics such as ciprofloxacin
* Medicines for treating high blood pressure
* Mifepristone (for termination of pregnancy) during the last 12 days
* Other non-steroidal anti-inflammatory drugs such as aspirin, ibuprofen, naproxen, diclofenac
* Selective serotonin reuptake inhibitor antidepressants (SSRI)
* Diuretics
* Zidovudine (for treating HIV)

## Use of the medicine and food

The medicine should be taken with or after a meal.

## Pregnancy and breastfeeding

If you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

Pregnancy

You should inform your doctor if you have difficulty becoming pregnant. Non-steroidal anti-inflammatory drugs may make it more difficult to become pregnant.

Do not use this medicine if you are in the last three months of pregnancy as it may harm the fetus or cause problems during delivery.

**The preparation may cause kidney and heart problems in the fetus. The preparation may affect the tendency of the mother or fetus to bleed and cause labor to be later or longer than expected.**

Do not take Etopan during the first six months of pregnancy unless it is absolutely necessary **and the doctor has recommended it**. If you need treatment during this period or while trying to get pregnant, take the lowest dose for the shortest possible time.

**Taking Etopan for more than a few days starting** from the 20th week of pregnancy can cause kidney problems in the fetus that can lead to low levels of amniotic fluid or narrowing of a blood vessel (ductus arteriosus) in the fetus' heart. If you need treatment for more than a few days, your doctor may recommend additional monitoring.

Breastfeeding

Do not use Etopan while breastfeeding. It is not known if this medicine passes into breast milk. It is not recommended for use during breastfeeding unless considered essential by the doctor.

## Driving and using machines

Etopan may cause dizziness, drowsiness or visual disturbances. If you experience these symptoms, do not drive or operate dangerous machinery while taking Etopan.

## Important information about some of the ingredients of the medicine

## The medicine contains lactose. If you have been told by a doctor that you have an intolerance to some sugars, consult your doctor before starting treatment with this medicine.

## The medicine contains less than 1 millimole of sodium (23 mg) per dose, so it is essentially considered sodium-free.

# 3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen.

## The dosage and treatment regimen will be determined by the doctor only. The usual dosage is:

Treatment of arthritis: Initial treatment of 800-1200 mg per day divided into 2-4 doses and then maintenance treatment at a dose of 600-1200 mg per day divided into 2-4 doses.

Pain relief: Initial treatment of 400 mg per day and then 200-400 mg every 6-8 hours or 600 mg twice a day and then 600 mg once or twice a day, as needed.

## Do not exceed a total dose of 1200 mg per day!

If you are elderly, the doctor will make sure you are taking the lowest dose for the shortest time, due to the risk of serious side effects.

## Do not exceed the recommended dose.

* Swallow the medicine whole with a glass of water.
* Do not chew, crush or break!

## Use in children

Etopan is not recommended for use in children.

**If you have accidentally taken a higher dose** or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Symptoms of overdose include headache, nausea and vomiting, abdominal pain, blood in the stool or black tarry stools. In rare cases, diarrhea, disorientation, agitation, coma, drowsiness, dizziness, ringing in the ears, fainting and convulsions. In cases of significant overdose, kidney failure and liver damage are also possible.

**If you forgot to take this medicine** at the designated time, do not take a double dose. Take the dose at the regular time and consult your doctor.

Adhere to the treatment as recommended by the doctor.

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

**If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.**

# 4. Side effects

As with any medicine, using Etopan may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The most serious side effects are allergic reactions, heart failure, stroke, kidney failure, liver failure, inflammation of the pancreas and aseptic meningitis. If you suffer from any of the symptoms described below, **stop taking Etopan and refer to a doctor immediately.**

## Symptoms of allergic reactions:

* Wheezing, difficulty breathing or shortness of breath,
* Swelling of the face, lips, mouth or tongue,
* Extensive rash, peeling or blistering of the skin, persistent itching.

Symptoms of heart and circulatory disorders:

* Chest pain, high blood pressure, swelling of the ankles, palpitations, several types of anemia or other blood disorders, unexpected bruising and bleeding.

Symptoms of stomach and intestinal problems (digestive system):

* Blood in the stool,
* Black tarry stools,
* Vomiting blood or dark particles that look like coffee grounds.

Symptoms of kidney failure:

* Difficulty or pain when urinating, change in color of urine or urinating more or less frequently than usual.

Symptoms of liver failure and inflammation of the pancreas:

* Jaundice (yellowing of the eyes or skin), abdominal pain, abnormal liver function test results.

Symptoms of aseptic meningitis

A serious and rare case of aseptic meningitis may occur in patients with other autoimmune diseases such as lupus or mixed connective tissue disease.

The symptoms of aseptic meningitis are:

* Very high fever, vomiting, headaches, a rash with spots that do not disappear when pressure is applied to the skin (may not develop), stiff neck, sensitivity to light, drowsiness and convulsions.

**Additional side effects**

* Sensory disorders such as headaches, ringing or buzzing in the ears, dizziness, abnormal vision, hallucinations, tingling, pricking and burning sensation of the skin (pins and needles), and vertigo (a sensation that objects around you are moving or spinning).
* Digestive system problems such as mouth ulcers, mouth pain, nausea, vomiting, abdominal discomfort, diarrhea, constipation, flatulence (gas), heartburn, indigestion.
* Skin disorders such as tissue swelling, skin itching, rash, redness.
* General disorders such as fever, drowsiness, fatigue, weakness, insomnia, tremors, nervousness, depression, confusion.

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

**Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) which directs you to the online form for reporting side effects, or by entering

the link: https://sideeffects.health.gov.il

# 5. How should the medicine be stored?

* Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, 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) that appears on the package. The expiry date refers to the last day of that month.

## Storage conditions

* Etopan 200/300/400: Store below 25°C.
* Etopan 500: Store below 25°C. Store in a cool and dry place.
* Do not dispose of medicines in the sewage or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

# 6. Further information

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

Etopan 200, capsules:

Lactose monohydrate, microcrystalline cellulose, povidone, magnesium stearate, colloidal silicon dioxide; Capsule shell contains gelatin, water, titanium dioxide, sodium lauryl sulphate, iron oxide red, iron oxide black, FD&C Red 3.

Etopan 300, capsules:

Lactose monohydrate, microcrystalline cellulose, povidone, magnesium stearate, colloidal silicon dioxide; Capsule shell contains gelatin, water, titanium dioxide, sodium lauryl sulphate, iron oxide red.

Etopan 400, tablets:

Lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate; Tablet coating contains hydroxypropyl methyl cellulose, titanium dioxide, PEG 400, iron oxide red, iron oxide yellow.

Etopan 500, tablets:

Lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate; Tablet coating contains hydroxypropyl methyl cellulose, titanium dioxide, PEG 400, D&C Yellow #10 Aluminium Lake, FD&C Blue #1 Aluminium Lake and FD&C Red #40 Aluminium Lake.

## What the medicine looks like and the contents of the pack:

Etopan 200, capsules:

Dark pink gelatin capsule, printed with "ETO 200 MG" in black on the capsule body and cap, filled with white to off-white powder.

The capsules are packaged in blisters. Each package contains 5, 20, 30 or 100 capsules.

Etopan 300, capsules:

Light pink gelatin capsule, printed with "ETO 300 MG" in black on the capsule body and cap, filled with white to off-white powder.

The capsules are packaged in blisters. Each package contains 6, 30 or 100 capsules.

Etopan 400, tablets:

Capsule-shaped, peach-colored, film-coated tablet. Engraved on one side: "T88".

The tablets are packaged in blisters. Each package contains 10, 12, 30 or 100 tablets.

Etopan 500, tablets:

Elliptical, blue, film-coated tablet. Engraved on one side: "TARO", on the other side: "89".

The tablets are packaged in blisters. Each package contains 4, 20 or 30 tablets.

Not all pack sizes may be marketed.

## Manufacturer and registration holder name and address:

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

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

| 10570.29074 | Etopan 200 |
| --- | --- |
| 10571.29075 | Etopan 300 |
| 10569.28990 | Etopan 400 |
| 11492.29689 | Etopan 500 |

Revised in September 2023 in accordance with the guidelines of the Ministry of Health.

For simplicity and clarity, this leaflet was phrased in the masculine gender. However, the medicine is intended for both genders.

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| **For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the following code:**  **For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:**  A qr code with black squares Description automatically generated A qr code on a white background Description automatically generated A qr code on a white background Description automatically generated A qr code on a white background Description automatically generated  Etopan 200   | **Etopan** | | --- | | **200** |   Etopan 300   | **Etopan** | | --- | | **200** |   Etopan 400   | **Etopan** | | --- | | **200** |   Etopan 500   | **Etopan** | | --- | | **200** |   **<https://israeldrugs.health.gov.il/#!/medDetails/105%2070%2029074%2000>**  **<https://israeldrugs.health.gov.il/#!/medDetails/105%2071%2029075%2000>**  **<https://israeldrugs.health.gov.il/#!/medDetails/105%2069%2028990%2000>**  **<https://israeldrugs.health.gov.il/#!/medDetails/114%2092%2029689%2000>**  For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.  For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664. |