Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

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

Inactive ingredients and allergens in this medicine: 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 your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

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

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

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (etodolac) or to any of the other ingredients in this medicine (see section 6).
- You have **severe heart failure.**
- You have an ulcer (a 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, stomach bleeding or perforation.
- You have had an **allergic reaction or asthmatic reaction** (wheezing, itching or skin rash) after taking aspirin, Etopan or another NSAID.
- You have severe liver failure and kidney failure.
- **You are in the last trimester of pregnancy**.
- You have previously had bleeding from the stomach or bowel due to taking a NSAID.

Special warnings about using this medicine

Before using Etopan, tell your doctor if:

- You have a kidney, heart or liver disease, or a blood disorder, especially if you are also taking diuretics. The dose should be as low as possible and you should have periodic tests.

- You are already on long-term therapy with a medicine other than Etopan, since your doctor will want to perform regular tests, especially if you are elderly.
- You suffer from fluid retention (swelling of legs, ankles or feet).
- You suffer from high blood pressure or heart failure.
- You suffer or have ever suffered from asthma or breathing difficulties.
- You have heart problems, have previously had a stroke or 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).

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

Serious gastrointestinal side effects such as bleeding, ulceration and perforation may occur at any time during treatment, with or without warning symptoms, in patients treated with NSAIDs. If you experience any sign of gastrointestinal bleeding, **stop** using Etopan **immediately**.

If you have a blood or urine test, tell your doctor that you are taking Etopan, as the medicine may affect the results.

Children and adolescents
Etopan is not recommended for use in children.

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

- anti-thrombotic medicines such as warfarin (blood thinner) and aspirin (prevention of platelet aggregation)
- ciclosporin or tacrolimus (used following organ transplantations)
- digoxin - for heart problems
- lithium - for mental illnesses
- methotrexate - to treat conditions such as psoriasis or rheumatoid arthritis
- corticosteroids (such as prednisolone)
- quinolone antibiotics e.g. ciprofloxacin
- medicines for treatment of hypertension
- mifepristone (for pregnancy termination) within the last 12 days
- other NSAIDs e.g. aspirin, ibuprofen, naproxen, diclofenac
- selective serotonin reuptake inhibitor (SSRI) antidepressants
- diuretics
- zidovudine (for treatment of HIV)

Using this medicine and food
Take the medicine with or after a meal.

Pregnancy and breastfeeding
If you are pregnant, breastfeeding, think you are pregnant or are trying to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy
You should inform your doctor if you have problems becoming pregnant. NSAIDs may make it more difficult to become pregnant.

Do not use the medicine if you are in the last 3 months of pregnancy, as it could harm your foetus or cause problems at delivery.
The medicine may cause kidney and heart problems in the foetus. The medicine may affect the maternal or foetal tendency to bleed and cause labour to be later or longer than expected. Do not take Etopan during the first 6 months of pregnancy, unless absolutely necessary **and advised by your doctor**. If you need treatment during this period or while you are trying to become pregnant, take the lowest dose for the shortest period possible.
Taking Etopan for more than a few days from 20 weeks of pregnancy onward can cause kidney problems in the foetus, which may lead to low levels of amniotic fluid (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the foetal heart. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

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

Driving and using machines
Etopan may cause dizziness, drowsiness or abnormal vision. If you experience these symptoms, do not drive or operate dangerous machines while taking Etopan.

Important information about some of this medicine's ingredients
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before starting treatment with this medicine.

This medicine contains less than 1 mmol (23 mg) sodium per dose, therefore it is considered essentially sodium-free.

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. The recommended dosage is usually:

Treatment of arthritis: Initial treatment with 800-1200 mg per day divided into 2-4 doses, followed by maintenance therapy at the dosage of 600-1200 mg per day divided into 2-4 doses.

Pain relief: Initial treatment with 400 mg per day, followed by 200-400 mg every 6-8 hours or 600 mg twice a day, followed by 600 mg once-twice per day, as required.

Do not exceed the overall dosage of 1200 mg per day!

If you are an elderly person, your doctor will make sure that you take the lowest dose for the shortest period of time due to the risk of severe side effects.

Do not exceed the recommended dose.
- Swallow the medicine whole with a glass of water.
- Do not chew, split or crush!

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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Symptoms of overdose include headache, nausea and vomiting, abdominal pain, blood in faeces or black tarry stool. On rare occasions, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting and seizures may occur. In cases of significant overdose, kidney failure and liver damage are also possible

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> 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. <u>Side effects</u>
As with any medicine, using Etopan may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience 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 effects described below, **stop taking Etopan and contact your doctor immediately**.

<u>Symptoms of allergic reactions:</u>
- Wheezing, difficulty breathing or shortness of breath,
- Swelling of the face, lips, mouth or tongue,
- Extensive rash, peeling or blistering of the skin, continuous itching.

<u>Symptoms of heart and blood circulation disorders:</u>
- Chest pain, high blood pressure, swelling of the ankles, palpitations, several types of anaemia or other blood disorders, unexpected bruising and bleeding.

<u>Symptoms of stomach and bowel (gastrointestinal) problems:</u>
- Blood in faeces,
- Black tarry stool,
- Vomiting blood or dark particles that look like coffee grounds.

<u>Kidney failure symptoms:</u>
- Difficulty or pain when passing urine, discolouration of urine or urinating more or less often than usual.

<u>Symptoms of liver failure and inflammation of the pancreas:</u>
- Jaundice (yellowing of the eyes or skin), abdominal pain, abnormal liver function test results.

Aseptic meningitis symptoms:
A serious rare condition known as aseptic meningitis may occur in patients with other autoimmune conditions such as systemic lupus erythematosus or mixed connective tissue disease.

The symptoms of aseptic meningitis are:

- A very high fever, vomiting, headaches, a blotchy rash that does not fade upon applying pressure to the skin (this may not develop), neck stiffness, photosensitivity, drowsiness and seizures.

Additional side effects

- Sensory disorders such as headaches, ringing or buzzing in the ears, dizziness, abnormal vision, hallucinations, tingling, pricking and burning of the skin (pins and needles), vertigo (a sensation that all the objects around you are moving or spinning).
- Gastrointestinal problems such as mouth ulcers, sore mouth, nausea, vomiting, abdominal discomfort, diarrhoea, constipation, flatulence (gas), heartburn, indigestion.
- Skin disorders such as swelling of tissues, itching of the skin, rash, redness.
- General disorders such as fever, drowsiness, tiredness, weakness, sleeplessness, shaking, nervousness, depression, confusion.

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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.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 your 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
- Etopan 200/300/400: Store below 25˚C.
- Etopan 500: Store below 25˚C. Store in a cool and dry place.
- Do not throw away medicines 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, this 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 contents of the pack:

Etopan 200, capsules:
Dark pink gelatin capsules, with "ETO 200 MG" printed in black on the body and cover of the capsule, filling of white to off-white powder.
The capsules are packed in blisters. Each pack contains 5, 20, 30 or 100 capsules.

Etopan 300, capsules:
Light pink gelatin capsules, with "ETO 300 MG" printed in black on the body and cover of the capsule, filling of white to off-white powder.
The capsules are packed in blisters. Each pack contains 6, 30 or 100 capsules.

Etopan 400, tablets:
Capsule-shaped peach coloured film-coated tablet, with "T88" embossed on one side.
The tablets are packed in blisters. Each pack contains 10, 12, 30 or 100 tablets.

Etopan 500, tablets:
Ellipse-shaped blue film-coated tablet, with "TARO" embossed on one side and "89" on the other side.
The tablets are packed in blisters. Each pack contains 4, 20 or 30 tablets.

Not all pack sizes may be marketed.

Manufacturer's and registration holder's name and address:
Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

Registration numbers of the medicine in the Ministry of Health National Drug Registry:

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

Revised in September 2023 according to Ministry of Health guidelines.

For further information about this medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:

Etopan 200	Etopan 300	Etopan 400	Etopan 500

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/128%2008%2030651%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.