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

The medicine is dispensed with a doctor's prescription only

Etodolac Teva 400 mg

Tablets

Composition:

Each tablet contains:

Etodolac 400 mg

For information on the inactive and allergenic ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

This medicine is not recommended for children and infants.

1. WHAT IS THE MEDICINE INTENDED FOR?

A nonsteroidal, anti-inflammatory preparation to relieve chronic or acute pain, especially joint pain (osteoarthritis, rheumatoid arthritis).

Therapeutic group:

Nonsteroidal 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 of the medicine (detailed in section 6 – "Further Information").
- You are sensitive to other nonsteroidal anti-inflammatory pain relievers, such as aspirin or ibuprofen.
- You are in the last trimester of pregnancy.
- You have experienced in the past shortness of breath, nasal inflammation (stuffy or runny nose), or urticaria (an allergic skin reaction) after taking aspirin, ibuprofen or another nonsteroidal anti-inflammatory medicine.
- You suffer from severe heart, liver or kidney failure.
- You have experienced gastrointestinal bleeding or perforation in the digestive system as a result of taking another nonsteroidal anti-inflammatory medicine.
- You suffer from a peptic ulcer (an ulcer in the stomach or duodenum) or you have had two or more incidents of a peptic ulcer, stomach bleeding or perforation.

Special warnings regarding use of the medicine:

- Nonsteroidal anti-inflammatory medicines may slightly increase the risk of heart attack or stroke. The risk is higher at high dosages and after prolonged treatment. Do not exceed the recommended dosage or duration of treatment.
- If you have heart problems, you have suffered in the past from a stroke or think you may be at risk for these conditions (e.g., if you have high blood pressure, diabetes or high cholesterol, or you are a smoker) – discuss the treatment with the doctor.
- Tell the doctor if you have unusual complaints regarding your digestive system during early stages of treatment, particularly vomiting blood, bloody or black stools, and especially if you are elderly.

Before treatment with Etodolac Teva, tell the doctor if:

- You have heart, liver or kidney problems or you suffer from a blood disorder
- You are suffering, or have suffered in the past, from asthma or breathing difficulties
- You are suffering from fluid retention (swelling of the legs, ankles and feet)
- You are suffering from heart failure or high blood pressure
- You have a mixed connective tissue disease, such as lupus
- You have a disease that affects digestion, such as ulcerative colitis or Crohn's disease
- You are undergoing long-term treatment with another medicine, since the doctor will want to perform regular tests, especially if you are an adult
- You are taking diuretics
- You have any signs of gastrointestinal bleeding
- You are sensitive to any food or medicine

Children and adolescents:

Etodolac Teva is not recommended for use in children.

Tests and follow-up:

Your doctor may decide to perform several blood, kidney and liver function tests during the course of treatment with this medicine.

Drug interactions:

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

- Medicines for treatment of hypertension
- Blood thinners, such as warfarin
- Medicines called cardiac glycosides, such as digoxin (to treat heart problems)
- Cyclosporin or tacrolimus (used after organ transplants)
- Methotrexate (to treat rheumatoid arthritis or psoriasis)
- Lithium (to treat mental illnesses)
- Mifepristone (for the termination of pregnancy)
- Other nonsteroidal anti-inflammatory medicines, such as aspirin, ibuprofen
- Corticosteroids, such as prednisolone
- Quinolone antibiotics (such as ciprofloxacin, levofloxacin, ofloxacin)
- Antidepressants of the selective serotonin reuptake inhibitors (SSRI) group
- Antiplatelet medicines to prevent blood clotting (such as aspirin, dipyridamole, clopidogrel)
- Diuretics
- Zidovudine (to treat HIV)

Use of the medicine and food:

The medicine can be taken with or after a meal.

Pregnancy and breastfeeding:

- If you are pregnant, think you are pregnant, are trying to become pregnant or are breastfeeding – refer to the doctor before using the medicine.
- Use of the medicine may make it difficult to become pregnant. Inform the doctor if you are planning to become pregnant or are having a hard time becoming pregnant.
- Do not use the medicine if you are in the last trimester of pregnancy.
- Do not use the medicine during the first two trimesters of pregnancy unless the doctor has instructed you otherwise.
- This preparation has a possible side effect of kidney damage in the fetus and low amniotic fluid starting from the 20th week of pregnancy. It is recommended to avoid the use of preparations from the NSAID group starting from 20th week of pregnancy and to consult a healthcare professional if necessary.
- The medicine has not been proven to be safe for use in breastfeeding women. If you are breastfeeding – refer to a doctor.

Driving and operating machinery:

Etodolac Teva may cause drowsiness, tiredness, dizziness and vision disturbances. If you experience these symptoms, do not drive or operate dangerous machinery.

Important information about some of the ingredients of the medicine:

The medicine contains lactose. If you have been told in the past by a doctor that you have an intolerance to certain sugars, refer to your doctor before taking this medicine.

This medicine contains less than 23 mg sodium per tablet and is considered sodium-free.

The medicine contains the coloring agent, Allura Red AC, which may cause allergic reactions.

3. HOW SHOULD YOU USE THE MEDICINE?

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

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

Antirheumatic: Initial treatment of 800-1200 mg per day, divided into 2-4 doses, followed by a maintenance dosage of 600-1200 mg per day, divided into 2-4 doses.

Pain relief: Initial treatment of 400 mg per day, followed by 200-400 mg every 6-8 hours or 600 mg twice a day, followed by 600 mg one to two times a day, as needed.

Do not exceed a total dosage of 1200 mg per day!

If you are elderly, the doctor will confirm that you are taking the lowest dose and for the shortest period of time, due to risk of severe side effects.

Do not exceed the recommended dose.

- Swallow the medicine whole with a glass of water.
- The tablets can be halved.
- There is no information regarding chewing/crushing/pulverizing.

If you accidentally took a higher dosage, 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.

The symptoms of overdose are: headache, nausea and vomiting, upper abdominal pain (above the navel), vomiting blood, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears (tinnitus), fainting and sometimes seizures.

If you forgot to take this medicine at the required time, take a dose as soon as you remember, unless it is nearly time to take the next dose. Do not take two doses together to compensate for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

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

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

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

4. SIDE EFFECTS

As with any medicine, use of Etodolac Teva 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.

Stop using the medicine and immediately refer to a doctor if:

- You experience indigestion or heartburn
- Upper abdominal pain appears, you vomit blood, blood appears in the stool, bleeding from the anus, inflammation of the colon, mouth ulcers
- You are suffering from allergic reactions such as rash, itching, blistering of the skin, discoloration (pallor), swelling, wheezing or shortness of breath
- Appearance of aseptic meningitis (neck stiffness, headaches, nausea or vomiting, fever, disorientation) has been reported primarily in patients with lupus or other mixed connective tissue disease
- Appearance of Stevens-Johnson syndrome (very rare), inflammation or blistering of the skin, mouth or tongue and/or inflammation of the eyes with increased sensitivity to light that may be severe and accompanied by a general unwell feeling

Additional side effects:

- Nausea or vomiting, diarrhea, flatulence, constipation, worsening of colitis or Crohn's disease
- Gastritis
- Pancreatitis (very rare)
- Swelling, high blood pressure and heart failure
- Fever, weakness, feeling ill, shortness of breath, abnormal vision, headache, unusual sensations such as burning or tingling in the hands or feet, depression, confusion, hallucinations, ringing in the ears (tinnitus), dizziness (including vertigo), tiredness, tremor, sleep difficulties (insomnia), drowsiness
- Anemia, sore throat, fever, unexpected bleeding
- Yellowing of the skin or whites of the eyes
- Increased need to urinate, difficulty in passing urine or discoloration of urine
- Changes in liver function and changes in the blood – can only be detected by blood tests
- Vascular inflammation (vasculitis)
- A feeling of rapid heartbeats (palpitations)
- Slightly increased risk of heart attack or stroke

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 "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that 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 any other medicine, should be kept in a safe 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 the 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.
- **Store in a dry place, below 25°C.**
- Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, hydroxypropylmethylcellulose, magnesium stearate, titanium dioxide, colloidal silicon dioxide, polyethylene glycol 6000, Macrogol, FD&C red #40/Allura Red AC aluminium lake, polysorbate 80, FD&C blue #2 aluminium lake, D&C yellow #10 aluminium lake.

Each tablet contains 142 mg lactose monohydrate and 0.67 mg to 1 mg sodium.

What the medicine looks like and the contents of the package

Pink, capsule shaped, film-coated tablet, with a score line on one side of the tablet and plain on the other side.

Each package contains 30 tablets.

Name of Manufacturer and License Holder and its Address:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020.

This leaflet was revised in July 2021 according to MOH guidelines.

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

131.63.30998

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