

PATIENT INFORMATION LEAFLET

DOLARIT 400 mg Film Tablet

It is taken orally.

Active Ingredient: Each film coated tablet contains 400 mg Etodolac.

Excipients: Microcrystalline cellulose, Lactose monohydrate (obtained from cow's milk.), Polyvinyl pyrrolidone, Sodium starch glycolate, Colloidal silicon dioxide, Magnesium stearate, Polyvinyl alcohol, Polyethylene glycol, Tribasic calcium phosphate, Talc, Titanium dioxide.

Before you start using this medicine, carefully read this INSTRUCTIONS FOR USE, because it contains important information for you.

- Keep this user manual. You can need to read again.
- If you have other questions, please talk your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not give it to others.
- During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.
- Follow exactly what is written in this instruction. Do not use high or low doses other than the dose recommended to you about the drug..

In this Instructions for Use:

- 1. What is DOLARIT and what is it used for?**
- 2. Things to consider before using DOLARIT**
- 3. How to use DOLARIT?**
- 4. What are the possible side effects?**
- 5. Storing DOLARIT**

Headings are included.

1. What is DOLARIT and what is it used for?

DOLARIT; It is a film-coated tablet containing etodolac as the active ingredient. DOLARIT is in the group of drugs (non-steroidal anti-inflammatory) used in the treatment of conditions characterized by inflammation.

DOLARIT; It is indicated for the treatment of signs and symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and acute gouty arthritis, and for the treatment of short and long-term pain such as acute musculoskeletal pain, postoperative (post-operative) pain, dysmenorrhea (painful menstruation).

2. Things to consider before using DOLARIT

DO NOT USE DOLARIT in the following situations.

If,

- If you are allergic to any component of DOLARIT,
- If you have experienced a severe allergic reaction (for example, severe skin rash, hives, difficulty in breathing, swelling in the nose due to allergy due to bronchial constriction, headache) to any drug from the drug group including aspirin or DOLARIT (for example: ibuprofen, celecoxib). return)
- May cause an increased risk for serious, sometimes fatal, heart and blood vessel problems (eg heart attack). The risk may be higher if you have heart problems, suffer from heart failure, or have been taking DOLARIT for a long time. If you have recently had or will have by-pass heart surgery,
- If you are in the last 3 months of your pregnancy,
- If you have or have had stomach ulcers in the past.

USE DOLARIT CAREFULLY in the following situations.

Risks related to the cardiovascular system

NSAIDs can increase the risk of potentially fatal thrombotic (clotting-related) events, heart attack, and stroke. This risk may increase with the duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at higher risk.

DOLARIT should not be used to treat pain prior to coronary artery bypass surgery.

Risks related to the digestive system

NSAIDs cause serious undesirable effects, such as bleeding, sores, perforation of the stomach or intestines, which can be fatal. These undesirable effects can occur at any time, with or without a pre-warning symptom. Elderly patients are at higher risk for these serious effects.

If you suffer from any of the following diseases, tell your doctor.

- Discontinue the use of the drug when there are complaints of bleeding, ulceration and perforation (perforation) in the digestive system.

If;

- If you are pregnant or planning to become pregnant or breastfeeding,
- If you are taking any prescription or nonprescription medicine, herbal product or any other dietary supplement and diuretic medicine,
- If you are allergic to drugs, food or other substances,
- If you have a history of kidney or liver disease, diabetes (diabetes) or stomach or bowel problems,
- If you have swelling or fluid accumulation, skin disease on the nose and cheeks (lupus), asthma, swelling in the nose caused by allergies or inflammation in the mouth,
- If you have or are at risk of high blood pressure, blood disorders, bleeding or clotting problems, heart problems (eg heart failure) or cardiovascular disease,
- If you are in poor health, have dehydration or low fluid volume or low blood sodium levels, drink alcohol or have a history of alcohol abuse,
- Use with caution if you have problems such as asthma or breathing difficulties.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using DOLARIT with food and drink

Do not take DOLARIT with alcohol, the risk of stomach damage may increase. You can use DOLARIT on an empty stomach or on a full stomach.

Pregnancy

Consult your doctor or pharmacist before using this medication.

DOLARIT can harm the fetus. If you are pregnant, planning a pregnancy and think you may be pregnant, do not use DOLARIT, contact your doctor.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

It is not known if DOLARIT is found in breast milk, do not breast-feed while taking DOLARIT.

Vehicle and machine use

DOLARIT may cause dizziness or lightheadedness. Patients should be aware of how they react to this medicine before driving or using machinery.

Important information about some excipients in the content of DOLARIT

If you have had a reaction (reaction) to DOLARIT or any of its ingredients, do not use this medicine.

DOLARIT contains 275 mg of lactose monohydrate. If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose; that is, it can be considered essentially “sodium-free”.

Concomitant use with other drugs

Tell your doctor if you are taking any medication, especially if you are taking any of the following:

- Medicines that prevent or delay blood clotting (Anticoagulants, eg, warfarin, heparin containing medicines), aspirin, corticosteroids (eg, prednisone containing medicines), medicines containing fluoxetine used in the treatment of depression [selective serotonin reuptake inhibitors (SSRIs)]. There may be an increased risk of stomach bleeding when taken with these drugs.
- The risk of side effects of DOLARIT may increase when drugs containing phenylbutazone (an anti-inflammatory drug used especially in rheumatic conditions) or probenecid (used to treat

gout by increasing uric acid excretion) are used.

- Drugs and groups whose effects may increase when used with DOLARIT are as follows; cyclosporine used in organ transplants, digoxin used in heart problems, lithium used in the treatment of certain mood disorders, methotrexate used in the treatment of conditions such as rheumatoid arthritis (a persistent disease that causes pain and deformity in the joints) or psoriasis, quinolones (for example, drugs containing ciprofloxacin) or sulfonylureas (for example, medicines containing glipizide),
- Groups and drugs whose effects may be reduced when used with DOLARIT Angiotensin-converting enzyme (ACE) inhibitors (eg drugs containing enalapril) or diuretics (eg drugs containing furosemide, hydrochlorothiazide).
- Do not take other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, mifepristone (used to terminate pregnancy), aspirin while using DOLARIT without consulting your doctor.

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3. How to use DOLARIT?

Instructions for proper use and dose/frequency of administration:

Do not take more than the recommended dose and do not take longer than your doctor's advice.

Application route and method:

DOLARIT is taken orally with a full glass of water, take it according to your doctor's instructions.

Different age groups:

Use in children:

DOLARIT should not be used in children younger than 18 years of age, safety and efficacy in these children have not been established.

Use in the elderly:

DOLARIT should be used with caution in elderly patients; they may be more susceptible to stomach bleeding and kidney problems.

Special use cases:**Kidney or liver failure:**

It can be used in mild to moderate hepatic and renal failure. It should not be used in severe **liver and kidney failure**.

If you have an impression that the effect of DOLARIT is too strong or weak, talk to your doctor or pharmacist.

If you use more DOLARIT than you should:

Signs (symptoms); Symptoms may include decreased urination, loss of consciousness, seizures, severe dizziness or lightheadedness, severe nausea or abdominal pain, slow or troubled breathing, unusual bleeding or bruising, vomiting like coffee grounds.

If you have used more than you should use from DOLARIT, talk to a doctor or pharmacist.

If you forget to use DOLARIT:

If you neglected to take a dose of DOLARIT and are taking it regularly, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose. Then keep taking it regularly.

Do not apply a double dose to make up for forgotten doses.

Effects that may occur when treatment with DOLARIT is terminated

No withdrawal symptoms were reported when DOLARIT treatment was terminated.

4. What are the possible side effects?

Like all medicines, there may be side effects in people who are sensitive to the substances contained in DOLARIT.

Side effects are listed as shown in the following categories:

Very common: may occur in at least 1 in 10 patients

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients

Very rarely seen in less than 1 in 10,000 patients

Not known: cannot be estimated from the available data

If any of the following occur, stop using DOLARIT and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Serious stomach ulcers or bleeding may occur with the use of DOLARIT. Taking high doses or for a long time, smoking or drinking alcohol increases the risk of these side effects. Taking DOLARIT with food does not reduce the risk of these effects. you have severe stomach or back pain; if you have black stools (melena); If you are vomiting blood or coffee grounds, or if you experience unusual weight gain or bloating, contact your doctor or emergency room immediately.
- Severe allergic reactions (skin rash; hives; itching; difficulty breathing; chest tightness; swelling of the mouth, face, lips or tongue).

These are all very serious side effects.

If you have one of these, it means you have a serious allergy to DOLARIT. You may need emergency medical attention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor immediately or go to the nearest hospital emergency department:

Common:

- Tiredness
- dizziness
- depression
- irritability
- blurred vision
- tinnitus
- Indigestion
- Abdominal pain
- Diarrhea
- Stomach gas
- nausea
- vomiting
- Constipation
- Inflammation of the stomach (gastritis)
- Itching
- rash

- Difficulty urinating
- Frequent urination
- shaking
- Fire

Uncommon:

- Blood Collection
- anemia
- Prolongation of bleeding time
- Severe disease in which white blood cells are reduced or completely destroyed in the blood and bone marrow
- Decrease in the number of leukocytes in the blood
- Presence of neutrophils in the blood
- Poisoning as a result of organs losing their functions
- Water collection of the body (edema)
- High sugar in patients with diabetes
- Change in body weight
- Taste disorder
- insomnia
- napping
- numbness
- clouding of consciousness
- eye inflammation
- temporary visual impairment
- Fear of Light
- Hearing loss
- high blood pressure
- heart failure
- flushing
- palpitations
- Fainting
- Vascular inflammation
- irregular heartbeats
- Heart attack

- Obstruction of the blood vessels feeding the brain

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storing DOLARIT

Keep DOLARIT out of the sight and reach of children and in its package.

Store at room temperature below 25°C and in its original packaging.

Use in accordance with the expiration date.

Do not use DOLARIT after the expiry date on the package.

Do not use DOLARIT if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder

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