

PATIENT INFORMATION LEAFLET

DOLARIT 300 mg film tablet

Oral administration only

Active Ingredient: Each tablet contains Etodolac 300 mg.

Excipients: Microcrystalline cellulose, Lactose monohydrate (Obtained from cow's milk.), Polyvinyl pyrrolidone K30, Sodium starch glycolate, Colloidal silicon dioxide, Magnesium stearate, Polyvinyl alcohol, Polyethylene glycol 400, Polyethylene glycol 6000, Tribasic calcium phosphate, Talc, Titanium dioxide.

Please read this leaflet carefully before you start taking/using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or your pharmacist.*
- *This drug has been prescribed for you personally, do not give it to others.*
- *If you go to the hospital or doctor while using this medicine, tell your doctor that you are taking it*
- *Follow the instructions in these leaflet. Do not use **high or low doses** other than the recommended dose.*

In this leaflet:

- 1. What is DOLARIT and what is it used for?***
- 2. Things to consider before using DOLARIT***
- 3. How to use DOLARIT?***
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Headlines are included.

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

DOLARIT is film coated tablet which contains 300 mg Etodolac as an active ingredient.

DOLARIT belongs group of drugs (non-steroidal antiinflammatory) used in the treatment of conditions characterized by inflammation.

DOLARIT is indicated for the treatment of the following diseases:

- Degenerative joint disease, joint calcification (Osteoarthritis),
- Rheumatic disease with joint inflammation (rheumatoid arthritis)
- A rheumatic disease (Ankylosing spondylitis), which is seen with joint and loss of movement especially in the spine joints
- Joint inflammation that occurs suddenly from time to time due to a problem in the breakdown of protein, often manifested by inflammation in the big toe, causing severe pain, tenderness, redness and swelling on the joints (acute gouty arthritis)
- Acute musculoskeletal pain
- Post-operative inflammation, swelling and soft tissue damage (Post-operative pain)
- Pain due to menstrual pain (dysmenorrhea) in women

2. What you need to know before you take DOLARIT

DO NOT take DOLARIT.

- If you are allergic (hypersensitive) to etodolac or any of the ingredients of DOLARIT,
- If you have ever had a severe allergic reaction (for example, severe skin rash, hives, difficulty breathing, pedunculated and benign growths in the tissue inside the nasal cavity (nasal polyp)) to any drug from the drug group including aspirin or DOLARIT (for example: ibuprofen, celecoxib) , dizziness)
- It can cause a high risk for serious, sometimes fatal, heart and blood vessel problems (eg heart attack). The risk may be higher if you have heart problems, if you have heart failure, or if you have been taking DOLARIT for a long time. If you have recently had by-pass heart surgery, or will soon
- If you are in the last 3 months of pregnancy,
- If you have or have ever had ulcers or bleeding in your stomach or intestines
- If you have ever had a history of gastrointestinal bleeding or perforation, or associated with pain medication,
- If you have severe heart, kidney or liver failure,
- If you are under the age of 18

USE DOLARIT CAREFULLY in the following situations.

Risks related to the cardiovascular system

Non-steroidal anti-inflammatory drugs (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 in the treatment of pain before coronary artery bypass surgery.

Risks related to the digestive system

Non-steroidal anti-inflammatory drugs (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 are suffering from any of the following diseases, tell your doctor.

- If there are signs of bleeding, ulcer and perforation in the digestive system, stop the use of the drug immediately.

If:

- If you are pregnant, or are planning to become pregnant or are breastfeeding,
- If you are taking any medication by prescription or over-the-counter, herbal product or any other dietary supplement and diuretic,
- If you are allergic to medicines, foods or other substances,
- If you have a history of kidney or liver disease, diabetes, or stomach or intestinal problems,
- If there is fluid accumulation in the body, a skin disease on the nose and cheeks called lupus, asthma, a pedunculated and benign growth in the tissue in the nasal cavity (nasal polyp) or inflammation in the mouth,
- If you experience high blood pressure, blood disorders, bleeding or clotting problems, heart problems (eg heart failure) or cardiovascular disease, or if you are at risk of any of these diseases,
- If you are in poor health, dehydrated or have low fluid volume or low blood sodium levels, are drinking or have a history of alcohol abuse,
- If you have problems such as asthma or difficulty breathing use with caution.

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

Taking DOLARIT with food and drink

Do not take DOLARIT with alcohol, the possibility of stomach irritation (gastric mucosa irritation) may increase. You can use DOLARIT with or without food.

Pregnancy

Consult your doctor or pharmacist before using this medication.

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

If you notice 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 whether DOLARIT passes into breast milk, do not breast-feed while taking DOLARIT.

Driving and using machines

DOLARIT may cause dizziness or lightheadedness. These effects may become more pronounced when taken with alcohol or certain medications. Do not drive or do other potentially unsafe work until you know how to react to DOLARIT.

Important information about some of the ingredients of DOLARIT

If you have experienced a reaction to DOLARIT or any of its ingredients before, do not use this medicine.

DOLARIT contains 206.3 mg of lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains less than 1 mmol (23 mg) of sodium per dose; it can be considered as "sodium-free".

Concomitant use with other drugs

If you are taking any medication, especially if you are taking any of the following, tell your doctor.

- Drugs that prevent or delay blood coagulation (anticoagulants, eg warfarin, heparin containing drugs), aspirin, corticosteroids (eg drugs containing prednisone), fluoxetine containing drugs used to treat depression (selective serotonin reuptake inhibitors (SSRIs)). The risk of stomach bleeding may increase when taken with these medications.

- The use of medicines containing phenylbutazone (especially an anti-inflammatory drug used in rheumatic situations) or probenecid (used in the treatment of gout by increasing uric acid excretion) may increase the risk of side effects of DOLARIT.

- Drugs and groups for which the effects can be increased when used in combination with DOLARIT;

Cyclosporine which is used organ transplantation, digoxin used in hearth problems, lithium used in the treatment of mood disorders, methotrexate for the treatment of conditions such as rheumatoid arthritis (a continuous disease causing joint pain and malformation) or psoriasis, quinolones (e.g., drugs containing ciprofloxacin) or sulfonylureas (e.g., drugs containing glipizide).

- Groups and medicines that may be less effective when used with DOLARIT ; Angiotensin-converting enzyme (ADE) inhibitors (eg enalapril containing drugs) or diuretics (eg furosemide, hydrochlorothiazide containing drugs).

- Do not take other non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, naproxen, diclofenac or mifepristone (used to terminate pregnancy without consulting your doctor), when using DOLARIT.

Please tell your doctor or pharmacist if you are taking or you have recently taken any other medicines, including medicines obtained without a prescription.

3. How to use DOLARIT?

Instructions for proper use and dose / application frequency:

Your doctor will tell you the dose and frequency to be taken according to the severity of your condition. If deemed necessary, it may be recommended to continue treatment with other forms of DOLARIT.

No more than 4 tablets should be taken in a day.

Administration route and method

DOLARIT is taken orally with and after meals, with a full glass of water.

Always take your medicine according to your doctor's instructions.

Do not chew or break the tablets in your mouth.

Different age groups:

Use in children:

DOLARIT should not be used in children under 18 years of age, and their safety and efficacy

has not been confirmed in these children.

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 failure or liver failure:

As with other drugs in this group, it should be used with caution against kidney or liver failure. In long-term use, the dose should be low and kidney and liver functions should be reviewed regularly.

Please ask your doctor if you think that the effect of DOLARIT is too strong or too weak.

If you take more DOLARIT than you should

Signs (symptoms); decreased urination, headache, nausea, vomiting, abdominal pain, gastrointestinal bleeding (dark or bloody stools or vomit may indicate bleeding), infrequently diarrhoea, hyperexcitability (excitation), coma, dizziness, drowsiness, tinnitus, feeling faint, very rarely convulsions and breathing difficulties may occur.

Talk to a doctor or pharmacist if you have used more of DOLARIT than you should.

If you forget to take DOLARIT

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

Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with DOLARIT is terminated

No withdrawal symptoms were reported when DOLARIT was discontinued.

4. What are the possible side effects?

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

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

- Severe stomach or back pain,

- Serious stomach ulcers or bleeding (Taking high doses or for a long time, smoking or drinking alcohol increase the risk of these side effects. Taking the drug with food does not reduce the risk of these effects),
- Blackening of stool color (melena), vomiting such as blood or coffee grounds (these symptoms may be a sign of bleeding in the gastrointestinal tract),
- Unusual weight gain or bloating
- Severe allergic reactions (skin rash, hives, itching, difficulty breathing, chest tightness, swelling of the mouth, face, lips or tongue),
- Stroke,
- Chest pain
- Fast or irregular heartbeat.

These are all very serious side effects. If you have one of these, it means you have a serious allergy to EDOLAR. You may need emergency medical attention or hospitalization. All of these very serious side effects are very rare.

Side effects are listed as shown in the following categories:

Very common	: Can be seen in at least 1 in 10 patients
Common	: Less than one in 10 patients, but more than one in 100 patients.
Uncommon	: less than one in 100 patients, but more than one in 1,000 patients.
Rare	: Less than one in 1,000 patients, but more than one in 10,000 patients
Very rare	: Less than one in 10,000 patients
Unknown	: Unable to estimate from the available data

Common

- Tiredness
- Dizziness
- Mental depression (depression)
- Irritability
- Blurred vision
- tinnitus
- Indigestion
- Abdominal pain

- Diarrhea
- Gas in the gut
- Nausea
- Constipation
- Inflammation of the stomach
- Black stool
- Vomiting
- Itching
- Rash
- Painful urination
- Frequent urination
- Chills and fever

Uncommon

- bruising on the skin
- Anemia
- Decreased platelets in the blood
- Increase in bleeding time
- Decrease in white blood cell and red blood cell values
- Anemia caused by the destruction of red blood cells (hemolytic anemia)
- Edema
- Increase in serum creatinine, a value indicating kidney function
- Increased blood sugar in previously controlled diabetic patients
- Change in body weight
- Taste disturbance
- Insomnia
- Impairment of consciousness
- Drowsiness
- Confusion
- Light sensitivity
- Temporary visual impairment
- Inflammation of the eye
- Deafness
- High blood pressure
- Congestive heart failure

- Facial flushing
- Palpitation
- Fainting
- Vascular inflammation
- Cardiac arrhythmia
- Heart attack
- Damage to the brain by occlusion of cerebral vessels
- Asthma
- Pulmonary edema (pulmonary infiltration) with elevated white blood cells (eosinophilia)
- Airway inflammation (bronchitis)
- Shortness of breath
- Pharyngeal inflammation
- cold
- Inflammation of the air-filled cavities (sinus) around the nose, temples, forehead and eyes
- Thirst
- Dry mouth
- Mouth sores
- Eating disorder
- Belching
- Inflammation of the small intestine
- Gastric wound and/or perforation with or without bleeding
- Intestinal wound
- Pancreatic inflammation
- Inflammation of the esophagus with or without contraction of the muscle between the esophagus and stomach
- Inflammation of the large intestine
- Elevated liver enzymes
- Inflammation of the liver caused by the bile duct (hepatitis)
- Liver inflammation
- Jaundice from bile duct
- Jaundice
- Liver failure
- Liver damage
- Edema of the skin

- Sweating
- Skin rash
- Rash with blistering on the skin
- Inflammation of veins on the skin with a raised red rash on the skin
- A disease with painful red or purplish rashes and blisters on the skin (Stevens-Johnson Syndrome)
- A life-threatening skin disease characterized by blistering and peeling of the skin (Toxic Epidermal Necrolysis)
- A skin disease that causes redness, blisters and sores in the mouth, eyes and genital area (Erythema Multiforme)
- Darkening of the skin color
- Hair loss
- Widespread red rash that is flat in some areas and raised from the skin in some areas (Maculopapular rash)
- Light sensitivity
- Increase in blood urea nitrogen
- Kidney failure
- Kidney disorder
- Renal cell damage
- Bladder inflammation
- Blood in the urine
- Kidney stone
- Kidney inflammation
- Irregularities of bleeding in the uterus
- Hypersensitivity reactions
- Serious allergic reactions (including shock) that begin suddenly and can lead to death, generally with symptoms such as redness, itching, throat swelling and drop in blood pressure.
- Disease picture (infection) resulting from the entry of disease-causing microbes or parasites into the body
- Headache
- Skin peeling

If you encounter any side effects not mentioned in these instructions for use, please inform your doctor or pharmacist.

5. Storage of DOLARIT ?

Keep DOLARIT out of the reach of children and in its packaging.

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

Use in accordance with the expiry date.

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

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

Marketing Authorization Holder

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