

# ETOTIO 400 mg/8 mg Film-Coated Tablet

For oral use. · Authorization No: - · ATC: -

Prescription Only

Muscle Relaxant

NSAID

Not for use under 18 years of age

## ACTIVE AND EXCIPIENTS

**Active ingredient:** Each film-coated tablet contains 400 mg Etodolac and 8 mg Thiocolchicoside.

**Excipients:** In the tablet core; lactose monohydrate (derived from cow's milk), microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, polyvinylpyrrolidone, magnesium stearate. In the film coating; hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol 400.

**Packaging:** Presented in carton boxes containing blister packs of 14 film-coated tablets.

**Before you start using this medicine, please read this PACKAGE LEAFLET carefully, as 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 pharmacist.

This medicine has been prescribed for you personally, do not pass it on to others.

During the use of this medicine, if you go to a doctor or hospital, tell your doctor that you are using this medicine.

Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose recommended for you regarding this medicine.

## IN THIS PACKAGE LEAFLET:

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## What is ETOTIO and what is it used for?

ETOTIO is a white or whitish, oblong film-coated tablet containing Etodolac and Thiocolchicoside as active ingredients.

ETOTIO is presented in carton boxes containing blister packs of 14 film-coated tablets.

### INDICATION 1

**Osteoarthritis**

**INDICATION 2**

**Painful syndromes of the spine (vertebral column)**

**INDICATION 3**

**Extra-articular rheumatism**

**INDICATION 4**

**For symptomatic treatment of painful muscle spasms**

**INDICATION 5**

**Pain occurring after trauma and surgery**

## Things to consider before using ETOTIO

### DO NOT use ETOTIO in the following situations:

If you have an allergic reaction to Etodolac, Thiocolchicoside, or any of the other excipients in ETOTIO,

If you have experienced a severe allergic reaction to any medicine from the group including Aspirin or Etodolac (e.g., severe skin rash, hives, difficulty breathing, swelling in the nose due to allergy accompanied by narrowing of the bronchi, dizziness),

If you have or have had ulcers or bleeding in your stomach or intestines,

If you have had gastrointestinal bleeding or perforation previously or associated with painkiller medicines,

If you have severe heart, kidney, or liver failure,

May cause a high risk for serious, sometimes fatal, heart and blood vessel problems (e.g., heart attack). The risk may be higher if you have heart problems, heart failure, or have been taking Etodolac for a long time. If you have recently undergone or will soon undergo bypass heart surgery,

If you are pregnant or breastfeeding,

If you have muscle weakness (inability to contract muscles),

If you are likely to become pregnant and are not using an effective method of birth control,

If you are under 18 years of age.

### USE ETOTIO CAREFULLY in the following situations:

**Cardiovascular risks:** Non-steroidal anti-inflammatory drugs (NSAIDs) may increase the risk of fatal thrombotic events (related to clotting), heart attack, and stroke. This risk may increase with the duration of use. The risk may be higher in patients with cardiovascular disease or those with risk factors for cardiovascular disease. ETOTIO should not be used for pain treatment before coronary artery bypass graft (CABG) surgery.

**Gastrointestinal risks:** Non-steroidal anti-inflammatory drugs (NSAIDs) cause serious unwanted effects that can be fatal, such as bleeding, ulceration, and perforation of the stomach or intestines. These unwanted effects can occur at any time, with or without warning symptoms. Elderly patients are at higher risk for these severe effects. Discontinue use of the medicine if you experience gastrointestinal bleeding, ulceration, or perforation.

If you are taking any prescription or non-prescription medicines, herbal products, or dietary supplements, or other diuretics,

If you have allergies to medicines, foods, or other substances,

If you have a history of kidney or liver disease, diabetes, or stomach or intestinal problems,

If you have swelling or fluid retention, lupus (a skin disease characterized by inflammation of capillaries on the nose/cheeks, large red patches on the skin), asthma, swelling in the nose due to allergy, or inflammation in the mouth,

If you have high blood pressure, blood disorders, bleeding or clotting problems, heart problems (e.g., heart failure) or cardiovascular disease, or if you are at risk of any of these diseases,

If you are in poor health, dehydrated, have low fluid volume, or low blood sodium levels, if you consume alcohol or have a history of alcohol abuse,

If you have problems such as asthma or difficulty breathing,

If you have epilepsy or are at risk of epileptic seizures.

One of the substances formed in the body when the active ingredient Thiocolchicoside in ETOTIO is used can cause damage to some cells (abnormal chromosome number) when Thiocolchicoside is used in high doses. This has been shown in animal and laboratory studies. This cellular damage in humans can pose a risk factor for cancer, harm the unborn child, and cause infertility in men. Therefore, strictly adhere to the dose and duration of treatment specified in the "Instructions for proper use and dose/application frequency" section. Do not use the medicine in higher doses or for more than 7 days. If you have any other questions, please consult your doctor.

If you notice signs of liver damage (e.g., loss of appetite, nausea, vomiting, abdominal discomfort, fatigue, dark urine, jaundice, itching) during treatment with ETOTIO, you should immediately stop using ETOTIO and seek medical attention if any such symptoms occur.

If diarrhea occurs during treatment, discontinue ETOTIO.

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

### **Using ETOTIO with food and drink**

Do not take ETOTIO with alcohol, as the risk of stomach damage may increase. ETOTIO can be used with food and drink.

### **Pregnancy**

*Consult your doctor or pharmacist before using the medicine.*

Do not take this medicine if you are pregnant, may become pregnant, or think you might be pregnant.

Do not take this medicine if you are a woman of childbearing potential not using contraception.

This medicine may harm your unborn child.

This medicine may cause problems with male fertility due to potential damage to sperm cells (abnormal chromosome number). This finding is based on laboratory studies (See Section 2 "Warnings and precautions").

*If you notice that you are pregnant during your treatment, consult your doctor immediately.*

### **Breastfeeding**

*Consult your doctor or pharmacist before using the medicine.*

Do not use this medicine if you are breastfeeding. This is because the medicine passes into breast milk.

## Driving and using machines

ETOTIO may cause dizziness or drowsiness. These effects may be worse if taken with alcohol or certain medicines. According to clinical studies, Thiocolchicoside has no effect on psychomotor performance related to mental activity. However, since the drug is commonly associated with drowsiness and dizziness, be careful when driving or operating machinery. Do not drive or perform other potentially unsafe tasks until you know how you react to it.

## Important information about some excipients in ETOTIO

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

Each ETOTIO tablet contains 250 mg of lactose monohydrate (derived from cow's milk). If your doctor has previously told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## Using with other medicines

Inform your doctor if you are taking any medicines, especially any of the following:

Medicines that prevent or delay blood clotting (anticoagulants, e.g., warfarin, heparin-containing medicines), aspirin, corticosteroids (e.g., prednisone-containing medicines), fluoxetine-containing medicines used in the treatment of depression [selective serotonin reuptake inhibitors (SSRIs)]. The risk of stomach bleeding may increase when taken with these medicines.

When medicines containing phenylbutazone (an anti-inflammatory medicine used especially in rheumatic conditions) or probenecid (used in the treatment of gout by increasing uric acid excretion) are used, the risk of ETOTIO's side effects may increase.

Medicines and groups whose effects may be enhanced when used with ETOTIO include: Cyclosporine used in organ transplantation; digoxin used in heart problems; lithium used in the treatment of certain mood disorders; methotrexate used for conditions such as rheumatoid arthritis (a chronic disease causing pain and deformity in joints) or psoriasis, quinolones (e.g., ciprofloxacin-containing medicines) or sulfonylureas (e.g., glipizide-containing medicines).

Groups and medicines whose effects may be reduced when used with ETOTIO: Angiotensin-converting enzyme (ACE) inhibitors (e.g., enalapril-containing medicines) or diuretics (e.g., furosemide, hydrochlorothiazide-containing medicines).

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

It is not recommended to take ETOTIO with other medicines that have a muscle relaxant effect on the musculoskeletal system, as their effects may be enhanced. For the same reason, caution should be exercised if used with another medicine affecting smooth muscles, due to the increased frequency of unwanted effects.

Remember that this warning may also apply to products used some time ago or to be used in the future.

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

## How to use ETOTIO?

### Instructions for proper use and dose/application frequency:

The recommended and maximum daily dose is 1 film-coated tablet twice a day, to be taken every 12 hours. This means, do not use more than 2 ETOTIO tablets in one day. Do not use the medicine for more than 7 consecutive days.

### Route and method of administration:

ETOTIO is for oral use only. Do not chew the film-coated tablets. Take the tablets with a sufficient amount of water (e.g., a glass of water) after meals. Do not exceed the recommended dose and avoid long-term use.

Unless your doctor gives separate advice, follow these instructions. Do not forget to take your medicine on time.

Your doctor will tell you how long your treatment with ETOTIO will last. Do not stop treatment early because you will not get the desired result.

### **Different age groups**

#### **Use in children:**

Do not use this medicine in children under 18 years of age.

#### **Use in the elderly:**

Should be used with caution in the elderly, as they may be more susceptible to stomach bleeding and kidney problems.

### **Special use cases:**

#### **Renal/Hepatic insufficiency:**

Safety and efficacy in patients with renal/hepatic impairment have not been studied. Should not be used in severe liver and kidney failure.

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

### **If you use more ETOTIO than you should:**

Symptoms may include; decreased urine output, headache, nausea, vomiting, abdominal pain, gastrointestinal bleeding (dark or bloody stools or vomit may be a sign of bleeding), rarely diarrhea, extreme excitability, coma, dizziness, drowsiness, ringing in the ears, feeling faint, very rarely convulsions and difficulty breathing.

*If you have used more ETOTIO than you should, talk to a doctor or pharmacist.*

### **If you forget to use ETOTIO:**

If you miss a dose of ETOTIO and you take it regularly, take the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose. Then continue taking it regularly.

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

### **Effects that may occur when treatment with ETOTIO is stopped:**

Consult your doctor for detailed information about the effects that may occur when treatment with ETOTIO is stopped.

## **What are the possible side effects?**

Like all medicines, ETOTIO may cause side effects in people sensitive to its ingredients.

**If any of the following occurs, stop using ETOTIO and IMMEDIATELY notify your doctor or go to the emergency department of the nearest hospital:**

Severe stomach or back pain,

Severe stomach ulcers or bleeding (taking high doses or for a long time, smoking, or drinking alcohol increases the risk of

these side effects. Taking the medicine with food does not reduce the risk of these effects.),

Blackening of stool color (melena), vomiting blood or coffee-ground-like vomit (these symptoms may be a sign of gastrointestinal bleeding),

Unusual weight gain or swelling,

Severe allergic reactions (skin rash, hives, difficulty breathing, chest tightness, swelling of the mouth, face, lips, or tongue),

Stroke,

Chest pain,

Rapid or irregular heartbeat.

Swelling of the hands, feet, ankles, face, lips, or mouth or throat in a way that makes swallowing or breathing difficult.

Itching, swelling on the skin and mucous membranes (angioneurotic edema), severe allergic reactions (anaphylactic shock).

Hives (urticaria).

Fainting (vasovagal syncope).

Convulsions (seizures) (See 2. Things to consider before using ETOTIO),

Decrease in blood pressure (hypotension), temporary confusion.

These are all very serious side effects.

If you have any of these, it means you have a severe allergy to ETOTIO. You may need urgent medical intervention or hospitalization.

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

Liver inflammation (hepatitis) (See 2. Things to consider before using ETOTIO),

Pain or discomfort in the stomach (abdominal) area, loss of appetite, nausea, vomiting, yellowing of the skin or whites of the eyes (jaundice), urine darker than normal, itching, fever, and fatigue (these may be signs of liver problems).

Drowsiness, somnolence.

Itching.

Skin rashes.

These are all serious side effects. Urgent medical intervention may be required.

Side effects are classified as follows: Very common: May be seen in at least 1 in 10 patients. Common: May be seen in less than 1 in 10 patients but more than 1 in 100 patients. Uncommon: May be seen in less than 1 in 100 patients but more than 1 in 1000 patients. Rare: May be seen in less than 1 in 1000 patients but more than 1 in 10,000 patients. Very rare: May be seen in less than 1 in 10,000 patients. Unknown: Frequency cannot be estimated from available data.

#### Common

Fatigue

Dizziness

Depression

Nervousness

Blurred vision

Tinnitus

Indigestion (dyspepsia)

Abdominal pain

Diarrhea

Intestinal gas

Nausea

Constipation

Gastritis

Diarrhea, stomach pain (gastralgia)

Black stools

Vomiting

Itching

Rash

Painful urination

Frequent urination

Shaking and fever

Sensory disturbances such as numbness, tingling, or burning sensation (paresthesia)

Sleepiness characterized by dullness of consciousness; drowsiness (somnolence)

### Uncommon

Skin bruising

Anemia

Decrease in platelets in the blood

Increased bleeding time

Decrease in white blood cell and red blood cell counts

Anemia caused by destruction of red blood cells (hemolytic anemia)

Edema

Increase in serum creatinine, a value indicating kidney function

Increase in blood sugar in diabetic patients previously under control

Changes in body weight

Taste disorder

Insomnia

Confusion

Mental confusion

Light sensitivity

Temporary visual impairment

Intraocular inflammation

Deafness

High blood pressure

Congestive heart failure

Facial flushing

Palpitations

Fainting

Vasculitis

Cardiac arrhythmia

Heart attack

Brain damage due to blockage of cerebral vessels

Asthma

Pulmonary infiltration with elevated white blood cells (eosinophilia)

Airway inflammation (bronchitis)

Shortness of breath

Pharyngitis

Rhinitis

Inflammation of the air-filled cavities (sinuses) around the nose, temples, forehead, and eyes

Thirst

Dry mouth

Mouth sores

Eating disorder

Belching

Small bowel inflammation

Stomach ulcer and/or perforation, with or without bleeding

Intestinal ulcer

Pancreatitis

Esophagitis, with or without spasm or narrowing of the muscle between the esophagus and stomach

Colitis

Increased liver enzymes

Hepatitis of biliary origin

Hepatitis

Jaundice of biliary origin

Jaundice

Liver failure

Liver damage

Widespread skin edema

Sweating

Allergic skin reactions

Skin rash

Skin peeling

Rash with blistering of the skin

Skin vasculitis with raised red rash

A disease characterized by 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 causing redness, blisters, and sores in the mouth, eyes, and genital area (Erythema Multiforme)

Darkening of skin color

Hair loss

Widespread red rash, flat in some areas, raised in others (Maculopapular rash)

Photosensitivity

Increased blood urea nitrogen

Kidney failure

Kidney dysfunction

Kidney cell damage

Cystitis

Blood in urine

Kidney stones

Nephritis

Uterine bleeding irregularities

Hypersensitivity reactions

Severe allergic reactions (including shock) with symptoms such as general redness, itching, throat swelling, and decreased blood pressure, which start suddenly and can be fatal

Headache

Disease caused by entry of pathogenic microorganisms or parasites into the body (infection)

#### Rare

Skin irritation (hives)

Pain and burning in the throat, chest, and stomach (heartburn).

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

#### **Reporting of side effects**

If you experience any side effects, whether listed or not listed in the package leaflet, talk to your doctor, pharmacist, or nurse. Also, you can report the side effects you encounter to the Turkish Pharmacovigilance Centre (TÜFAM) by

clicking on the "Drug Side Effect Notification" icon on the [www.titck.gov.tr](http://www.titck.gov.tr) website or by calling the side effect notification line at 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

## How to store ETOTIO?

*Keep ETOTIO out of the sight and reach of children, and in its packaging.*

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

### **Use in accordance with the expiration date.**

*Do not use ETOTIO after the expiration date stated on the packaging.*

Do not dispose of expired or unused medicines in the trash! Hand them over to the collection system determined by the Ministry of Environment and Urbanization.

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

### **Marketing Authorization Holder:**

Gensenta İlaç Sanayi ve Ticaret A.Ş.

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### **Manufacturer:**

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