

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### **ETOL FORT**

400 mg film-coated tablets

ETODOLAC

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### **What is in this leaflet?**

- 1.What ETOL FORT is and what it is used for
- 2.Before you take ETOL FORT
- 3.How to take ETOL FORT
- 4.Possible side effects
- 5.How to store ETOL FORT
- 6.Further information

#### **1. WHAT ETOL FORT IS AND WHAT IT IS USED FOR**

ETOL FORT belongs to a group of medicines called non-steroidal anti-inflammatory medicines (NSAIDs).

It is used in the short-term treatment of the following conditions:

- Pain attacks caused by tendonitis (inflammation of the tendons) and bursitis (inflammation of the fluid-filled sacs located in the joints and which function is to reduce friction between tendons and bones, tendons and ligaments, and between bony prominences and skin)
- painful attacks of osteoarthritis (degenerative joint disease)
- back pain

Also, your doctor may prescribe this medicine for the treatment of other painful and inflammatory conditions.

#### **2. BEFORE YOU TAKE ETOL FORT**

**Do not take ETOL FORT:**

- If you are allergic (hypersensitive) to etodolac or to any other ingredients of ETOL FORT (see Chapter 6)
- if you are in sixth (6th) month of pregnancy
- If you have had an allergic reaction or asthmatic attack after taking acetylsalicylic acid or other non-steroidal anti-inflammatory medicines (NSAIDS)
- If you had an ulcer in the stomach, intestine, or stomach bleeding caused by NSAIDS
- If you've had or you constantly have gastric or duodenal ulcer
- If you have gastrointestinal, brain, or other active bleeding
- If you have serious liver disease
- If you have serious kidney disease
- If you have serious heart disease
- If you are under 15 years of age

**Be careful with ETOL FORT:**

Non-steroidal anti-inflammatory medicines (NSAIDS) may increase the risk of heart attack (myocardial infarction) or stroke. The risk is increased by the application of high doses and prolonged duration of treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, before you have had a stroke or think you might be at risk of developing such conditions (for example, if you have high blood pressure, diabetes, high cholesterol or are a smoker), you should talk about your treatment with your doctor or pharmacist.

This medicine should be used only under medical supervision.

**Before treatment**

Contact your doctor if:

- you have a history of asthma with chronic rhinitis (inflammation of the lining of the nose), chronic sinusitis (sinusitis) or nasal polyps (growths in the nasal cavities); This medicine may cause an asthmatic attack in people who are allergic to acetylsalicylic acid or other NSAIDS (see the section "do not take ETOL FORT")
- you have a coagulation disorder (blood clotting) or are receiving an anticoagulant and anti-thrombotic medicine; ETOL FORT can cause serious gastrointestinal intestinal problems
- you have a history of diseases of the gastrointestinal tract (gastric or duodenal ulcer, hiatus hernia, intestinal bleeding in the gastrointestinal tract)
- you have heart, liver and kidney disease
- you have gastrointestinal bleeding (blood in the mouth, stool, or black stools and Vertigo);
  - symptoms suggestive of hypersensitivity to the medicine, such as sudden swelling of the face and neck, and asthmatic attack; stop applying medicine and tell your doctor or emergency medical service

**Important information about your product**

Etol FORT may make it harder to get pregnant. Tell your doctor if you are planning to become pregnant or if you have difficulty in trying to become pregnant.

Contact your doctor or pharmacist for advice before using any medicine.

This medicine contains etodolac as active substance, which belongs to the group of nonsteroidal anti-inflammatory drugs (NSAIDs). You should not use other NSAIDs (including selective cyclooxygenase-2 inhibitors) and / or aspirin with ETOL FORT.

Read the leaflet of other medicines that you use to ensure that they do not contain NSAIDS or acetylsalicylic acid.

### ***Taking other medicines with ETOL FORT***

Tell your doctor and pharmacist if you are taking or have recently taken any other medicines, including those that can be obtained without a prescription.

Please inform your doctor or pharmacist if you are using some of the following medicines:

- acetylsalicylic acid or other NSAIDS
- corticosteroids
- blood thinners such as warfarin, heparin, antithrombotic (medicines that reduce the accumulation of platelets) or thrombolytic (medicines for dissolution thrombus), such as Ticlopidine
- lithium
- methotrexate
- inhibitors angiotensin converting enzyme, diuretics, beta-blockers, Angiotensin II angiotensin II
- certain antidepressants (selective inhibitors of serotonin to reuptake)
- pemetrexed
- Cyclosporine, Tacrolimus

### ***Food and drink***

There is no information.

### ***Pregnancy and breastfeeding***

If necessary, your doctor may prescribe this medicine during the first 5 months of pregnancy.

You should not take this medicine after 6 months of pregnancy, as this may cause the development of vascular and renal adverse effects even if it is applied only as one dose and the baby's development is complete.

However, in some cases, it is possible that the gynecologist prescribes this medicine, and in such situation, you need to strictly follow the doctor's instructions.

This medicine passes into breast milk, so it should not be used during breastfeeding.

### ***Driving and using machines***

ETOL FORT can cause headaches, light dizziness, fatigue. If any of these conditions occur to you, do not drive or operate machinery.

### ***Important information about some of the ingredients of ETOL FORT***

#### **Lactose**

ETOL FORT contains 146.50 mg of anhydrous lactose. In case of intolerance to some of the sugars, contact your doctor before using this medicine.

#### **Sodium**

ETOL FORT contains 34.50 mg of croscarmellose sodium which must be considered in patients who are on a diet with a controlled salt intake.

### ***3. HOW TO TAKE ETOL FORT***

ETOL FORT is taken through the mouth (oral administration).

Always take ETOL FORT exactly as explained by your doctor. If you are not sure, check with your doctor or pharmacist.

ETOL FORT should be swallowed with a glass of water. Take the tablet with food and swallow without chewing.

**Adults and adolescents older than 15 years:**

Acute pain

Adults - 200 to 400 mg every 6 to 8 hours. Daily doses higher than 1000 mg are not adequately tested in controlled clinical trials.

Osteoarthritis - the recommended daily dose of etodolac in the treatment of the signs and symptoms of osteoarthritis is 300 mg twice a day, three times a day or 400mg twice a day, or 500 mg two times a day. A dose of 600 mg per day may be adequate for long-term use. Doses higher than 1000 mg per day are not sufficiently tested in controlled clinical trials.

***If you take more of ETOL FORT than you should***

If you have taken a higher dose of ETOL FORT than you should, speak with your doctor or go to the nearest hospital. Bring the leaflet of this medicine with you so a doctor knows which medicine you have taken.

If you have any additional questions about the use of this medicine, ask your doctor or pharmacist.

***4. POSSIBLE SIDE EFFECTS***

Like all medicines, FORTE ETOL can cause side effects, although not everybody gets them.

Medicines such as ETOL FORT, can lead to a small increase in the risk of heart attack (myocardial infarction) or stroke.

***Very serious side effects***

Stop taking a medicine FORTE ETOL and contact your doctor or seek immediate medical attention if you notice the following symptoms:

- serious allergic reaction that causes:
  - different types of cutaneous reactions, such as rash, hives, nettle rash deterioration
  - respiratory problems: asthmatic attacks
  - in general: the rash is accompanied by swelling of the face, and throat
- rare bleeding may occur from the gastrointestinal tract (vomiting blood or blood in the stool)
- In addition to the above mentioned, you may experience:
  - gastrointestinal intestinal disorders, such as: stomach pain, vomiting, diarrhea, constipation, pain in the stomach
  - the other side effects associated with the use of this medicine: dizziness, headache, sleepiness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

***5. HOW TO STORE ETOL FORT***

Keep out of reach and sight of children.

Store at temperature below 25 ° C in the original package.

Do not use ETOL FORT after the expiry date stated on the carton. Shelf life is four years from the production date stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### **What ETOL FORT contains:**

408 mg of the active substance etodolac DC (98%), which corresponds to 400 mg of etodolac.

### **The other ingredients are:**

lactose, microcrystalline non hydrated cellulose PH 200, croscarmellose sodium (Ac-di-sol), silica-colloidal non hydrated (Aerosil 200), magnesium stearate, povidone (PVP K30, Polyvinylpolypyrrolidone). The film, covering material No: 43 -Opadry II pink (85F240035) contains: polyvinyl alcohol-partially hydrolyzed (E1203), titanium dioxide (E171), MACROGOL/PEG (E1521), talc (E553b) and red iron oxide (E172).

### **How ETOL FORT looks like and contents of the pack**

ETOL FORT film tablets are pale pink in color, oval in shape, with a notch on one side, and with the inscription "NOBEL" on the other.

Package with 14 film-coated tablets: 14 tablets/1 blister/1 box (14 tablets/1 blister)

### **Regime of dispensing**

The medicine is issued to the doctor's prescription

### **Manufacturer**

NOBEL İLAÇ SANAYİİ VE TİCARET A. Ş.  
İnkılap Mah. Akçakoca Sok. No: 10  
Ümraniye 34768 İstanbul Turkey

### **Manufacturer of the medicinal product**

NOBELFARMA İLAÇ SANAYİİ VE TİCARET A. Ş.  
Sancaklar 81100 Düzce Turkey