

## **Etodolac ER 600mg Film-coated extended release tablets**

### **Package leaflet: Information for the user**

#### **Etodolac ER 600mg tablets**

etodolac

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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. See section 4.

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

1. What Etodolac ER is and what it is used for
2. What you need to know before you take Etodolac ER
3. How to take Etodolac ER
4. Possible side effects
5. How to store Etodolac ER
6. Contents of the pack and other information

#### **1. What Etodolac ER is and what it is used for**

Etodolac ER is used to treat the symptoms of rheumatoid arthritis and osteoarthritis by

reducing inflammation, swelling, stiffness and joint pain. This medicine is released slowly which means that you only have to take one tablet each day.

Etodolac ER is one of a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs) which are usually taken to relieve pain, inflammation and stiffness often caused by osteoarthritis or rheumatoid arthritis.

#### **2. What you need to know before you take Etodolac ER**

##### **Do not take Etodolac ER**

- if you are allergic to etodolac or any of the other ingredients of this medicine (listed in section 6)
- if you have had an allergic reaction to other non-steroidal anti-inflammatory drugs such as aspirin or ibuprofen
- if you have experienced shortness of breath, rhinitis (blocked or runny nose) or urticaria (allergic skin reaction) when taking aspirin, ibuprofen or another non-steroidal anti-inflammatory drug
- if you have experienced gastrointestinal bleeding or perforation due to another non-steroidal anti-inflammatory drug
- if you have a peptic ulcer (ulcer in your stomach or duodenum) or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- if you have severe heart failure, liver failure or kidney failure

- if you are in your last trimester of pregnancy.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Etodolac ER

- if you have problems with your heart, liver or kidneys or suffer from a blood disorder
- if you have a mixed connective tissue disorder such as lupus (SLE)
- if you suffer from or have had asthma or breathing difficulties
- if you suffer from fluid retention, (swelling of legs ankles and feet)
- if you suffer from heart failure or high blood pressure
- if you are taking long term-therapy with a medicine other than Etodolac ER, as your doctor will want to arrange regular check-ups, especially if you are elderly
- if you have disease that affects your digestion such as ulcerative colitis or Crohn's disease
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- your doctor may carry out a number of blood, kidney function and liver function tests whilst you take Etodolac ER

- if you are currently taking "water-pills" (diuretics)
- if any signs of gastrointestinal bleeding.

Medicines such as Etodolac ER may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

### Children

Etodolac ER is not recommended for use in children.

### Other medicines and Etodolac ER

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Etodolac ER can react with some medicines, which can cause unwanted effects or prevent the medicines from working properly

- drugs used to treat high blood pressure
- drugs used to thin the blood e.g. warfarin
- drugs called cardiac glycosides such as digoxin (used to treat heart problems)
- ciclosporin or tacrolimus (used after an organ transplant)
- methotrexate (used to treat rheumatoid arthritis or psoriasis)
- lithium (used to treat mental illness)

- mifepristone (used for the medical termination of pregnancy)
- other non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen
- corticosteroids such as prednisolone
- quinolone antibiotics (e.g. ciprofloxacin, levofloxacin, ofloxacin)
- antidepressants called SSRIs
- drugs used to stop blood clotting called antiplatelet agents (e.g. aspirin, dipyridamole, clopidogrel)
- diuretics ('water-pills')
- zidovudine (used to treat HIV infection).

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Etodolac ER may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Do not use Etodolac ER in the last trimester of pregnancy.

Etodolac ER should not be used during the first two trimesters of pregnancy unless your doctor advises you otherwise.

Etodolac ER have not been established as safe for use in breast-feeding mothers.

### **Driving and using machines**

Etodolac ER may cause drowsiness, tiredness, dizziness and abnormal vision. Do not drive or operate machinery if you experience any of these symptoms.

### **Etodolac ER contains lactose and sunset yellow**

Lactose is an ingredient in Etodolac ER. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Etodolac ER contains orange yellow S E110. This may cause allergic reactions.

### **3. How to take Etodolac ER**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet taken daily.

If you are elderly, your doctor will make sure you take the lowest dose for the shortest time, as you may be more likely to have the serious side effects.

Take with or after food. Swallow the tablet whole with water, do not crush or chew the tablets.

### **Use in children**

Etodolac ER is not recommended for use in children.

### **If you take more Etodolac ER than you should**

If you or anybody else take(s) too many tablets call your doctor or contact your nearest hospital immediately. Symptoms of an overdose include headache, feeling and

being sick, pain in the upper abdomen (above the navel), vomiting blood, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears (tinnitus), fainting and occasionally convulsions.

#### **If you forget to take Etodolac ER**

If you forget to take a dose at the right time, take it as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to make up for a forgotten dose. Do not take more than one tablet in a single day.

#### **If you stop taking Etodolac ER**

Do not stop taking Etodolac ER without your doctor's permission.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking and seek immediate medicinal attention if you experience any of the following

- epigastric pain (upper abdomen), vomiting blood, bloody stools, bleeding from the anus, inflammation of the colon, ulcers of mouth
- heartburn, indigestion abdominal pain
- allergic reactions such as rash, itching, blistering of skin, discolouration, swelling, wheezing or shortness of breath

- aseptic meningitis (stiff neck, headache, feeling or being sick, fever, disorientation) has been reported particularly in patients with lupus (SLE) or other mixed connective tissue disease
- very rarely, Stevens-Johnson syndrome, inflammation or blistering of the skin, mouth or tongue and/or inflammation of the eyes with increased sensitivity to sunlight. These may be severe and be accompanied by feeling generally unwell.

#### **Other side effects**

- feeling or being sick, vomiting, diarrhoea, flatulence, constipation, worsening of colitis or Crohn's disease
- less frequently, gastritis (inflammation of the stomach lining)
- very rarely, inflammation of the pancreas (pancreatitis)
- swelling, high blood pressure and heart failure
- fever, weakness, feeling unwell, 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.
- anaemia, sore throat, fever, unexpected bleeding.

- yellowing of the skin or whites of the eyes
- increased need to urinate, difficulty passing urine or discolouration of urine
- changes in liver function and changes in the blood can only be detected by blood tests
- inflammation of blood vessels (vasculitis)
- feelings of having rapid, fluttering or pounding heart (palpitations)
- small increased risk of heart attack ("myocardial infarction") or stroke.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### 5. How to store Etodolac ER

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last date of that month.

Do not throw away any medicines via wastewater or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help with the environment.

#### 6. Contents of the pack and other information

##### What Etodolac ER contains

- The active substance is etodolac
- The other ingredients are:  
**tablet core:** microcrystalline cellulose, povidone, methyl hydroxypropyl cellulose, lactose anhydrous, magnesium stearate  
**tablet coat:** hypromellose, polydextrose, macrogol, triacetin, titanium dioxide, indigo carmine lake, orange yellow, allura red AC lake, black iron oxide and yellow iron oxide.

##### What Etodolac ER looks like and contents of the pack

Etodolac ER are grey, oval, convex shaped, tablets with "T600" debossed on one side and plain on the other side.

The tablets are supplied in blister packs of 30 or 100 tablets.

Not all pack sizes may be marketed.