

Etodolac 300mg/400mg Capsules USP

Package leaflet: information for the user

etodolac

Etodolac 300mg/400mg Capsules USP Taj Pharma

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. What etodolac capsules are and what they are used for

Etodolac Capsules belong to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Etodolac Capsules are used to relieve some of the symptoms caused by arthritis (Osteoarthritis and Rheumatoid arthritis) such as inflammation, swelling, stiffness and joint pain.

2. Before you take etodolac capsules

Do not take Etodolac Capsules if you

- are allergic (hypersensitive) to etodolac or any of the ingredients of Etodolac Capsules (see section 6).
- have had an allergic reaction after taking aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs). An allergic reaction may include swelling of the face or throat, a nettle rash, asthma or itchy and runny nose.
- have a peptic ulcer (a hole in the stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding.
- have had perforation related to previous non-steroidal anti-inflammatory drugs therapy
- have a severe heart failure, liver or renal failure
- are in the last three months of pregnancy (last trimester)

Take special care with Etodolac Capsules Tell your doctor or pharmacist before taking Etodolac Capsules if you:

- have any kidney or liver problems or heart problems, especially if you are also taking diuretics (water tablets) and are elderly. The dose should be as low as possible and you should have regular checks
- have a blood disorder
- have high blood pressure or heart failure
- suffer from fluid retention (swelling of legs, ankles, or feet)
- have or had bronchial asthma or breathing difficulties
- suffer from auto-immune disorders such as mixed connective tissue disease, systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).

Important information about your medicine

Medicines such as Etodolac 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.

Please speak to your doctor if you have any factors that may put you at a greater risk of suffering a heart attack or stroke such as:

- you are a smoker
- you have any heart problems
- you have high cholesterol
- you have high blood pressure
- You have diabetes

If you are told you need a blood test or urine test, tell your doctor you are taking **Etodolac Capsules** as the drug may affect the results.

Serious gastrointestinal side effects such as bleeding, ulceration and perforation can occur at any time with or without warning symptoms in patients treated with NSAIDs. If any sign of gastrointestinal bleeding occurs, **Etodolac Capsules** should be stopped immediately.

Serious skin reactions including allergic reactions such as extensive rash, peeling or blistering of the skin, continuous itching may appear during the early course of the therapy or within the first month of treatment. These reactions have been reported very rarely with the use of NSAIDs. If any sign of skin reactions occurs **Etodolac Capsules** should be stopped immediately.

Taking other medicines

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

Do not take Etodolac Capsules in combination with:

- other non-steroidal anti-inflammatory drugs (NSAIDs) such as **aspirin** or **ibuprofen**

Care is needed if you are taking

- **anti-coagulants such as warfarin** (used to prevent blood clotting)
- **ciclosporin, tacrolimus** (used to help with organ transplants)

- **cardiac glycosides** such as digoxin (used to treat certain heart problems)
- **lithium** (used to treat manic depression)
- **mifepristone** (used to terminate pregnancy)
- **methotrexate** (used to treat conditions such as cancer, or rheumatoid arthritis)
- **anti-hypertensives** such as diuretics, also called water tablets (medicines used to treat high blood pressure)
- antibiotics known as **quinolone** such as ciprofloxacin, ofloxacin or levofloxacin
- **corticosteroids** (used to treat skin rashes)
- **zidovudine** (used to treat HIV infection)
- **anti-platelet medicines** such as clopidogrel, ticlopidine (used to prevent blood clots)
- **selective serotonin reuptake inhibitor** such as sertraline, fluoxetine (medicines used to treat certain brain disorders).

Taking Etodolac Capsules with alcohol

Do not take alcohol while taking Etodolac. Stomach problems may be more likely to occur if you drink alcoholic beverages while being treated with this medicine.

Pregnancy and breast-feeding

Do not take Etodolac Capsules if you are pregnant, may be pregnant or are breast-feeding.

Etodolac Capsules 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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Etodolac Capsules may cause dizziness, drowsiness or visual disturbances in some individuals. **DO NOT** drive or operate machines if you are affected.

Important information about some of the ingredients of Etodolac Capsules

This medicine contains a small amount of an inactive ingredient **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take etodolac capsules

Always take Etodolac Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Take Eccoxolax Capsules by mouth with water. Take with or after food.

Adults and Elderly:

- The usual adult dose is one 300mg/400mg capsule twice a day.
- Alternatively, two 300mg/400mg capsules may be taken once a day.

The elderly have an increased risk of having side effects. A lower dose with a lesser duration may be recommended in elderly patients.

Your doctor will monitor you regularly for gastrointestinal side effects like bleeding during the therapy.

Children:

Etodolac Capsules are not recommended for use in children.

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

If you forget to take Etodolac Capsules at the right time, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you have taken more Etodolac Capsules than you should, consult your doctor or go to the nearest hospital casualty department immediately. Take this leaflet with you so your doctor will know what you have taken.

Symptoms of overdose include headache, nausea, vomiting, epigastric pain, passage of black tarry stools, diarrhoea, disorientation, excitation, drowsiness, dizziness, ringing in the ear, fainting, occasionally fits and coma. Kidney failure and liver damage have also been reported.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Etodolac Capsules can cause side effects, although not everybody gets them.

These side effects may be temporary. However, you should tell your doctor if the side effects are troublesome, or last for more than a few days. Medicines such as Etodolac capsules may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Very serious side effects

If any of the following happen, stop taking Etodolac Capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- serious allergic reaction which causes
 - swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
 - aggravation of asthma, asthma like reaction comprising of breathlessness, wheezing, feeling of tightness in the chest and shortness of breath
 - different kind of skin disorders such as rashes, itching, hives, unusual bleeding or bruising under the skin, flaking or peeling of the skin
- serious illness with blistering of the skin, mouth, eyes and genitals
- gastrointestinal bleeding (rectal bleeding, passage of black stools, vomiting of blood or material that looks like coffee grounds), severe abdominal or stomach pain. Gastrointestinal problems can occur in some individuals at any time following long-term treatment with this class of medicines (NSAIDs)

These side effects are very serious. You may need urgent medical attention.

Serious side effects

Tell your doctor as soon as possible or go to the casualty department at your nearest hospital if you notice any of the following:

- increases risk of bleeding or bruising. These symptoms may be due to reduction in blood platelets
- frequent infections such as fever, severe chills, sore throat or mouth ulcers due to lack of white blood cells
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. These symptoms may be due to infection around the brain or spinal cord (meningitis). This side effect has been reported especially in patients having systemic lupus erythematosus (allergic condition which causes joint pain, skin rashes and fever) or mixed connective tissue disease.
- visual disturbances, sudden dimming or loss of vision
- heart attack, heart problems which can cause shortness of breath or ankle swelling
- numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech. These symptoms may be due to damage to part

of the brain caused by an interruption to its blood supply (stroke)

- worsening of symptoms of colitis [inflammation of the colon (large bowel)]. Symptoms are diarrhoea, usually with blood and mucus, stomach pain, fever
- worsening of symptoms of Crohn's disease (an inflammatory disease that can affect any part of the gastrointestinal tract). Symptoms are pain, fever, diarrhoea and loss of weight
- severe pain in the abdomen and back often with nausea and vomiting. These symptoms may be due to inflammation of the pancreas
- liver problems such as jaundice (yellowing of the skin or whites of the eyes), liver function problems
- urinary problems such as high blood pressure, feet swelling, passing little or no urine or passing blood. These might be a sign of kidney failure or toxicity.

Other side effects

Tell your doctor if you notice any of the following:

- mental depression, headache, dizziness, trouble in sleeping, confusion, seeing or hearing things that are not real (hallucination), disorientation, nervousness, drowsiness or light-headedness
- sensation of numbness or tingling over the limbs
- shakiness or tremor
- swelling of legs, ankles or feet

- high blood pressure, throbbing of heart (palpitation)
- loose stool (diarrhoea), feeling or being sick (nausea or vomiting), indigestion, stomach pain, heart burn, constipation, wind
- mouth ulcers and cold sores
- pain when passing urine, urinating more or less often than usual
- inflammation of blood vessels, often with skin rash
- increased sensitivity of the skin to sunlight
- generally feeling unwell, tiredness, unusual weakness, chills and fever.

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

5. How to store etodolac capsules

Keep out of the reach and sight of children.

Store in the original package.

Do not use Etodolac Capsules after the expiry date that is stated on the outer packaging.

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 Etodolac Capsules contain:

- The active ingredient is Etodolac.

- Each capsule contains Etodolac USP 300mg/400mg.
- The other inactive ingredients are: lactose, anhydrous silica, sodium lauryl sulphate, sodium starch glycollate, povidone, magnesium stearate, microcrystalline cellulose and talc.

The hard gelatin capsules are coloured with sunset yellow (and iron oxide black).

The black ink contains shellac, iron oxide black, n-butyl alcohol, soya lecithin MC thin and antifoam.

What Etodolac Capsules look like and contents of the pack:

Etodolac 300mg/400mg Capsules

The capsules are available in blister strips of 10 or 15 capsules each in boxes of 60 capsules.

7. Manufactured By:

Taj Pharmaceuticals Ltd.

at: Plot. No. 220, Mahagujarat

Industrial Estate, At & Post-Moraiya,

Tal-Sanand, Dist- Ahmedabad Gujarat (India)