170 mm

520 mm

Package leaflet: Information for the patient
Etopan XL 600 mg 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, please 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. See section 4.

What is in this leaflet

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

1. What Etopan XL is and what it is used for

Etopan XL is used to treat the symptoms of rheumatoid arthritis and osteoarthritis by reducing inflammation, swelling, stiffness, and joint pain. Each tablet contains 600mg of the active ingredient etodolac. This medicine is released slowly which means that you only have to take one tablet each day.

Etopan XL is one of a group of medicines called "non-steroidal anti-inflammatory drugs" (NSAIDs) which are usually taken to relieve the pain, stiffness, inflammation and swelling which is often associated with arthritis.

2. What you need to know before you take Etopan XL

Do not take Etopan XL if you:
- are allergic to etodolac or any of the other ingredients of this medicine (listed in section 6)
- **have severe heart failure**
- have a peptic ulcer (a small erosion or hole in the stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- have had an **allergic reaction** or **asthmatic type reaction** (e.g. wheezing, itching or skin rash) after taking aspirin, etodolac or another NSAID
- have hepatic failure and renal failure
- are pregnant, think you may be pregnant or are breast feeding
- have previously taken similar medicines classed as NSAIDs and suffered with bleeding from the stomach or bowel.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Etopan XL or other painkillers (NSAIDs or acetylsalicylic acid)

Warnings and precautions
Talk to your doctor or pharmacist before taking Etopan XL
- If you suffer from kidney, heart or liver disease, or a blood disorder, especially if you are also taking diuretics (water tablets). The dose should be as low as possible and you should have regular checks
- If you are already on long-term therapy with a medicine other than Etopan XL, since your doctor will want to arrange regular check-ups, especially if you are elderly
- If you suffer from fluid retention, (swelling of legs, ankles or feet)
- If you suffer from high blood pressure or heart failure
- If you suffer from, or have ever suffered from, asthma or breathing difficulties
- 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)

Medicines such as Etopan XL 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.

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) you should discuss your treatment with your doctor or pharmacist.

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, Etopan XL should be **stopped immediately**.

This medicine can cause serious skin reactions. Stop using Etopan XL and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children
Etopan XL is not recommended for use in children**.**

Other medicines and Etopan XL
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking:
- warfarin - for blood thinning
- ciclosporin - following transplantation
- digoxin - for heart problems
- lithium - for mental illness
- methotrexate - used to treat conditions such as psoriasis or rheumatoid arthritis
- corticosteroids (such as prednisolone)
- quinolone antibiotics e.g. ciprofloxacin
- aspirin
- other NSAIDs e.g. ibuprofen, naproxen, diclofenac
- drugs to control high blood pressure
- mifepristone (a drug to induce abortion) in the last 12 days

If you have a blood or urine test, tell your doctor that you are taking Etopan XL, as the drug may affect the results.

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.

You should inform your doctor if you have problems becoming pregnant. NSAIDs may make it more difficult to become pregnant.

Do not take Etopan XL if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Etopan XL during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Etopan XL can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Etopan XL should not be used if you are breast-feeding. It is not known if this medicine passes into breast milk. It is not recommended for use during breast-feeding unless considered essential by your doctor.

Driving and using machines
Etopan XL may cause dizziness, drowsiness, or abnormal vision. If you find that you are affected in this way, you should not drive or operate machinery whilst taking.

Etopan XL contains lactose and sunset yellow
Lactose is an ingredient in Etopan XL. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Etopan XL contains orange yellow S E110. This may cause allergic reactions.

3. How to take Etopan XL

Always take this medicine exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure. Check the pharmacist's label for the dose recommended for you.

The recommended adult dose is one tablet taken daily. The tablet should be swallowed whole with a glass of water. Take with or after food. Do not chew or crush the tablet.

Use in children
Etopan XL is not recommended for use in children.

If you take more Etopan XL than you should
If you take more tablets than you should (an overdose), seek medical attention immediately. Always take the bottle (or packaging) with you, even if empty. Symptoms of overdose include headache, feeling sick, vomiting, stomach pain, passing blood in faeces or passing black tarry stools. On rare occasions diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, and convulsive fitting may occur. In cases of significant overdose kidney failure and liver damage are possible.

If you forget to take Etopan XL
Do not take a double dose to make up for the forgotten dose. Take your tablet as soon as you remember and continue to take your medicine as usual, but do not take more than one tablet a day.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The most serious side effects that may occur with Etopan are serious allergic or hypersensitivity reactions, heart failure, stroke, kidney failure, liver failure, inflammation of the pancreas and aseptic meningitis. If you suffer from any of the symptoms described below: **stop taking Etopan and call a doctor straight away**.

<u>Allergic or hypersensitivity reactions may have the following symptoms:</u>
- wheezing, difficulty breathing or shortness of breath,
- swelling of the face, lips, mouth or tongue,
- extensive rash, peeling or blistering of the skin, continuous itching.

<u>Skin reactions:</u>
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency not known).
- sudden, severe allergic reaction with itching, hives, breathing difficulty, facial/throat swelling, lightheadedness, dizziness, fast heartbeat, sweating and loss of consciousness (anaphylactic reaction) (frequency not known)

<u>Heart and blood circulatory disorders symptoms</u>:
- Chest pain, high blood pressure, swelling of the ankles, palpitations (throbbing of heart), several types of anaemia or other blood disorders, unexpected bruising and bleeding.

<u>Stomach and bowel (gastrointestinal) problems: If you</u>
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

<u>Kidney failure symptoms:</u>
- Difficulty or pain when passing urine, discolouration of urine or urinating more or less often than Usual

<u>Liver failure and inflammation of the pancreas symptoms</u>:
- Jaundice (yellowing of the eyes or skin), abdominal pain, abnormal liver function test results.

<u>Aseptic Meningitis symptoms</u>
A serious rare condition known as aseptic meningitis may occur in patients with other auto-immune conditions such as systemic lupus erythematosus or mixed connective tissue disease.
The symptoms of aseptic meningitis are:
- a very high temperature, being sick, a headache, a blotchy rash that does not fade when a glass is rolled over it (this may not develop), a stiff neck, a dislike of bright lights, drowsiness and fits.

<u>Other reported side effects are</u>:
- Sensory disorders such as headache, ringing or buzzing in ears, dizziness, abnormal vision, hallucinations, tingling, pricking and burning of the skin (pins and needles) and vertigo (a sensation that objects are moving or spinning).
- Gastrointestinal problems such as mouth ulcers, sore mouth, nausea, vomiting, stomach upsets, diarrhoea, constipation, wind, heartburn, indigestion.
- Skin disorders such as swelling of tissues, itching of the skin, rash, redness.
- General disorders such as fever, drowsiness, tiredness, weakness, sleeplessness, shaking, nervousness, depression, confusion.
- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

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

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. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etopan XL

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 protect the environment.

6. Contents of the pack and other information

What Etopan XL 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 E132, orange yellow S E110, allura red AC lake E129, black iron oxide E172 and yellow iron oxide E172.

What Etopan XL looks like and contents of the pack
Etopan XL 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.

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