

EBERIL 30mg/60mg/90mg/120mg Tablet

Etoricoxib (30mg, 60 mg, 90 mg and 120 mg)

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What Eberil is used for

Your doctor has prescribed Eberil Tablet for:

- Treatment of osteoarthritis
- Treatment of rheumatoid arthritis
- Treatment of ankylosing spondylitis
- Chronic low back pain (30mg and 60mg only)
- Treatment of acute pain after minor dental procedures
- Treatment of menstrual pain
- Treatment of gout attacks

Osteoarthritis is a joint disease. It results from the gradual breakdown of the cartilage that cushions the ends of the bones, resulting in pain, inflammation, tenderness, stiffness, and physical disability.

Rheumatoid arthritis is a chronic disease that causes pain, stiffness, swelling and loss of function in the joints and inflammation in other body organs.

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

Gout is a disorder characterized by sudden, recurring attacks of pain and inflammation in one or more joints.

How Eberil works

Eberil tablet is a member of a group of medicines called selective COX-2 inhibitors that are used to reduce pain and inflammation. Eberil tablet is not a narcotic.

Before you take Eberil

- When you must not use it

Do not take Eberil if you:

- are allergic to any of its ingredients
- have heart failure, a heart attack, bypass surgery, chest pain, narrow

or blocked arteries of the extremities, a stroke or mini stroke

- have high blood pressure that has not been controlled by treatment

- Before you start to use it

Tell your doctor about any medical problems or allergies you have now or have had, including:

- History of angina, heart attack or a blocked artery in your heart
- Narrow or blocked arteries of the extremities
- Kidney disease
- Liver disease
- Dehydration, for example by a prolonged bout of vomiting or diarrhea
- Have or have had ulceration, bleeding or perforation of your stomach or intestines
- Heart failure
- High blood pressure
- Swelling due to fluid retention
- An allergic reaction to Aspirin or other anti-inflammatory medicines (commonly known as NSAIDs)
- A history of stroke or mini stroke
- Conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking
- Being treated for an infection. Eberil tablet can mask or hide a fever, which is a sign of infection.
- Have had asthma, nasal inflammation, and/or itching or hives caused by Aspirin or NSAID
- Suffering from dyspepsia (indigestion).

Etoricoxib may cause severe skin reactions. Symptoms may include skin rash, blisters and peeling of the skin. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Use in children

Eberil tablet has not been adequately studied in children. Therefore, Eberil tablet should not be given to children.

Use in the elderly

Eberil tablet works equally well in older and younger adult patients. Adverse experiences may occur at a higher

incidence in older patients compared to younger patients. If you are elderly (i.e., over 65 years of age), your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for older patients.

Use in pregnancy and breastfeeding

Tell your doctor if you are:

- Eberil tablet may cause fetal harm and should not be used by a woman who is attempting to become pregnant or becomes pregnant during treatment.
- Breastfeeding or plan to breastfeed.

- Taking other medicines

You should always tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription.

Your doctor may want to check that your medicines are working properly if you are taking:

- Warfarin (a blood thinner)
- Rifampin (an antibiotic)
- Diuretics (water tablets)
- ACE inhibitors and angiotensin receptor blockers (medicines used for high blood pressure and heart failure)
- Lithium (a medicine used to treat a certain type of depression)
- Birth control pills
- Hormone replacement therapy
- Methotrexate (a medicine used for suppressing the immune system).

Eberil tablet can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because Eberil tablet cannot substitute for aspirin for this purpose.

How to take Eberil

- How much to take

Eberil tablet should be taken once a day. You may take Eberil tablet with or without food.

Your doctor will decide what dose of Eberil tablet you should take and how long you should take it.

For treatment of osteoarthritis:

- The recommended dose is 30 mg or 60 mg once a day.

For treatment of rheumatoid arthritis:

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- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

For treatment of ankylosing spondylitis:

- The recommended dose is 60 mg once a day, and may increase to 90 mg once a day if needed.

Chronic low back pain:

The recommended dose is 60 mg once daily.

Acute pain conditions

The recommended dose is 90 mg or 120 mg once daily. Eberil should be used only for the acute period limited to a maximum of 8 days.

For the relief of gout attacks and the treatment of menstrual pain:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after minor dental procedures

- The recommended dose is 90 mg once a day.

Doses greater than those recommended for each condition have either not demonstrated additional efficacy or have not been studied. Therefore, the daily doses stated above for each condition should not be exceeded.

If you have mild or moderate liver disease, your doctor might prescribe you a lower dose or recommend that you do not take Eberil.

- When to take it

- ♦ Use as directed by your doctor or pharmacist.

- How long to take it

- ♦ Continue taking Eberil tablet for as long as your doctor recommends.

- If you forget to take it

- ♦ Try to take Eberil tablet as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule the following day.

- If you take too much (overdose)

- ♦ If you take more than the prescribed dosage, contact your doctor immediately.

While you are taking Eberil tablet

- Things you must do

Consult your doctor if:

- Any of the following symptoms appear or worsen: shortness of breath, chest pains or ankle swelling. Stop your treatment with Eberil tablet and consult a doctor, as soon as is practical.
- You have kidney, liver or heart disease, your doctor will want to appropriately keep a check on you.
- You develop any symptoms that could indicate a severe allergic reaction such as inability to breath or a serious skin reaction, you must consult a doctor on an urgent basis.

Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that controls your pain.

Eberil tablet can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time, to make sure that it is safe to continue treatment.

- Things you must not do

Do not share Eberil tablet with anyone else; it was prescribed only for you.

Do not take Eberil tablet for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how Eberil affects you.

Eberil contains lactose

If you have been told by your doctor that you are unable to tolerate some sugars, contact your doctor before taking this medicinal product.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects.

Like all prescription medicines, Eberil tablet may cause side effects.

The following side effects can occur during treatment with Eberil:

- Dizziness
- Swelling of the legs and/or feet
- Weakness and fatigue
- High blood pressure
- Nausea
- Heartburn
- Upset stomach
- Headache
- Dry socket (inflammation and pain after a tooth extraction)

Additional side effects are:

- Allergic reactions (which may be serious enough to require immediate medical attention) including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, wheezing, rash, itching and hives
- Redness of the skin
- Severe skin reactions which may occur without warning
- Taste alteration
- Abnormal rhythm of the heart
- Heart failure
- Palpitations
- Feeling of tightness, pressure or heaviness in the chest
- Stomach pain
- Stomach ulcers that may become serious and may bleed and may occur at any time during use and without warning
- Vomiting
- Liver problems including liver failure, yellowing of the skin and eyes (jaundice)
- Serious kidney problems
- High levels of potassium in your blood
- Insomnia
- Anxiety
- Depression
- Restlessness
- Drowsiness
- Mouth ulcers
- Diarrhea
- Severe increase in blood pressure
- Confusion
- Hallucinations
- Platelets decreased
- Blurred vision

Other side effects may also occur rarely, and as with any prescription medicine,

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some side effects may be serious. Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Eberil

Storage

Keep medicines out of reach of children. Store at temperature of not more than 30°C.

Disposal

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 you protect the environment.

Product Description

- What it looks like

30 mg: Light green, apple-shaped, biconvex, film coated tablet with engraved 30 on one side and plain on the other side

60 mg: Green, apple-shaped, biconvex, film coated tablet with engraved 60 on one side and plain on the other side

90 mg: White, apple-shaped, biconvex, film coated tablet with engraved 90 on one side and scored on the other side

120 mg: Pale-green, apple-shaped, biconvex, film coated tablet with engraved 120 on one side and scored on the other side

- Ingredients

- Active ingredient:

Etoricoxib (30mg, 60 mg, 90 mg, 120 mg)

- Inactive ingredients:

Microcrystalline cellulose (Avicel PH 112), Crospovidone (Crospovidone XL-10), Anhydrous dibasic calcium phosphate,

Mannitol, Povidone (PVP K-30), Isopropyl alcohol, Croscarmellose sodium, Lactose monohydrate (Supertab), Poloxamer (Lutrol Micro 127), Colloidal silicon dioxide (Aerosil 200), Magnesium stearate, Hypromellose (HPMC 2910), Propylene glycol, Methylene chloride, Kollicoat IR [Combination of Polyvinyl alcohol units (75%); Polyethylene glycol units (25%); Colloidal anhydrous silica (Approx. 0.3%)], Titanium dioxide, Talc, Lake brilliant blue (C.I. No. 42090), Iron oxide red (C.I. No. 77491), Iron oxide yellow (C.I. No. 77492), Purified water, Polyethylene glycol (PEG 6000) and Copovidone (Kollidon VA 64)

- MAL Number:

30mg: MAL22116018AZ
60mg: MAL21046022AZ
90mg: MAL21046023AZ
120mg: MAL21046024AZ

Manufacturer

UNISON LABORATORIES CO., LTD.
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Product Registration Holder

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