

Torix®

Etoricoxib

Presenation:

Torix 90: Each Film coated tablet contains 90 mg Etoricoxib in packs 14 & 28 tablets.

Torix 120: Each Film coated tablet contains 120 mg Etoricoxib in packs 7 tablets.

Hospital packs are also available.

Not all pack sizes are available in all countries.

Excipients: Microcrystalline Cellulose, Croscarmellose Sodium, Povidone K-30, Dibasic Calcium Phosphate, Magnesium Stearate, Opadry II White, Yellow Iron Oxide, FD&C Blue # 1 Lake.

Pharmaceutical form:

Film coated tablets for oral use.

Pharmacotherapeutic group:

Nonsteroidal anti-inflammatory drugs; COX-2 selective inhibitor, ATC code: M01AH05

Therapeutic Indications:

• **Torix** helps to reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout.

• **Torix** is also used for the short term treatment of moderate pain after dental surgery.

Posology and method of administration:

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

Etoricoxib Tablets should not be taken by children or adolescents under 16 years of age.

Take **Torix** Tablets by mouth once a day. **Torix** can be taken with or without food.

Do not take more than the recommended dose for your condition. 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 and you should not take **Torix** for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

Osteoarthritis: The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis and Ankylosing spondylitis: The recommended dose is 90 mg once a day.

Acute pain conditions: Etoricoxib should be used only for the acute painful period.

Gout: The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

Postoperative dental surgery pain: The recommended dose is 90 mg once daily, limited to a maximum of 3 days treatment.

People with liver problems

- If you have mild liver disease, you should not take more than 60 mg a day.
- If you have moderate liver disease, you should not take more than 30 mg a day.

If you forget to take Torix

It is important to take **Torix** as your doctor has prescribed. If you miss a dose, just resume your usual schedule the following day. Do not take a double dose to make up for the forgotten tablet.

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

Taking Torix with food and drink

Torix tablets may be taken with or without food. The onset of the effect of **Torix** may be faster when taken without food.

Contra-indications:

- If you are allergic (hypersensitive) to Etoricoxib or any of the other excipients.
- If you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors.
- If you have a current stomach ulcer or bleeding in your stomach or intestines.
- If you have serious liver or kidney disease.
- If you are or could be pregnant or are breast-feeding.
- If you are under 16 years of age.
- If you have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis.
- If your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain) or if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries), or any kind of stroke (including mini-stroke, transient ischemic attack or TIA). Etoricoxib may slightly increase your risk of heart attack and stroke and this is why it should not be used in those who have already had heart problems or stroke.
- If you have high blood pressure that has not been controlled by treatment (check with your doctor if you are not sure whether your blood pressure is adequately controlled).

If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Warnings and Precautions for use:

Etoricoxib may not be suitable for you, or you may need to

be monitored regularly while taking it if any of the following apply to you:

- You have a history of stomach bleeding or ulcers.
- You are dehydrated, for example by a prolonged bout of vomiting or diarrhea.
- You have swelling due to fluid retention.
- You have a history of heart failure, or any other form of heart disease.
- You have a history of high blood pressure. Etoricoxib can increase blood pressure in some people, especially in high doses, and your doctor will want to check your blood pressure from time to time.
- You have any history of liver or kidney disease.
- You are being treated for an infection. Etoricoxib can mask or hide a fever, which is a sign of infection.
- You are a woman trying to become pregnant.
- You are elderly (i.e., over 65 years of age).
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.

If you are not sure if any of the above apply to you, talk to your doctor before taking Etoricoxib to see if this medicine is suitable for you.

Etoricoxib works equally well in older and younger adult 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 elderly patients.

• Driving and using machines:

Dizziness and sleepiness have been reported in some patients taking Etoricoxib.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

Use during Pregnancy and Lactation:

Pregnancy: Etoricoxib tablets must not be taken during pregnancy. If you are pregnant or think you could be pregnant, or if you are planning to become pregnant, do not take the tablets. If you become pregnant, stop taking the tablets and consult your doctor. Consult your doctor if you are unsure or need more advice.

Lactation: It is not known if Etoricoxib is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking Etoricoxib. If you are using Etoricoxib, you must not breast-feed.

Drug Interactions:

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

In particular if you are taking any of the following medicines, your doctor may want to monitor you to check that your medicines are working properly, once you start taking Etoricoxib:

- Medicines that thin your blood (anticoagulants), such as warfarin
 - Rifampicin (an antibiotic)
 - Methotrexate (a drug used for suppressing the immune system, and often used in rheumatoid arthritis)
 - Medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include Enalapril and Ramipril, and losartan and valsartan
 - Lithium (a medicine used to treat some types of depression)
 - Diuretics (water tablets)
 - Cyclosporine or Tacrolimus (drugs used for suppressing the immune system)
 - Digoxin (a medicine for heart failure and irregular heart rhythm)
 - Minoxidil (a drug used to treat high blood pressure)
 - Salbutamol tablets or oral solution (a medicine for asthma)
 - Birth control pills
 - Hormone replacement therapy
 - Aspirin, the risk of stomach ulcers is greater if you take Etoricoxib with aspirin.
- Etoricoxib can be taken with low-dose aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor
- do not take high dose aspirin or other anti-inflammatory medicines while taking Etoricoxib

Undesirable effects:

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

If you develop any of these signs you should stop Etoricoxib and talk to your doctor immediately:

- Shortness of breath, chest pains, or ankle swelling appears or if they get worse
- Yellowing of the skin and eyes (jaundice) – these are signs of liver problems
- Severe or continual stomach pain or your stools become black
- An allergic reaction, which can include skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing

The following side effects can occur during treatment with

Etoricoxib:

Common: Weakness and fatigue, dizziness, headache, flu-like illness, diarrhea, wind, nausea, indigestion (dyspepsia), stomach pain or discomfort, heartburn, changes in blood tests related to your liver, swelling of the legs and/or feet due to fluid retention (edema), increased blood pressure, palpitations, bruising , dry socket (inflammation and pain after a tooth extraction).

Uncommon: Stomach or bowel bloating, chest pain, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack, stroke, mini-stroke (transient ischaemic attack), abnormal heart rhythm (atrial fibrillation), upper respiratory infection, high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, changes in your bowel habits including constipation, dry mouth, mouth ulcers, taste alteration, gastroenteritis, gastritis, stomach ulcer, being sick (vomiting), irritable bowel syndrome, inflammation of the oesophagus, blurred vision, eye irritation and redness, nose bleed, ringing in the ears, vertigo, appetite increases or decreases, weight gain, muscle cramp/spasm, muscle pain/stiffness, inability to sleep, sleepiness, numbness or tingling, anxiety, depression, decreases in mental sharpness, breathlessness, cough, swelling of the face, flushing, skin rash or itchy skin, urinary tract infection, platelets decreased, decreased number of red blood cells, decreased number of white blood cells.

Rare: Low blood levels of sodium, redness of the skin.

Very Rare: Allergic reactions (which may be serious enough to require immediate medical attention) including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, bronchospasm (wheezing or shortness of breath), severe skin reactions, inflammation of the stomach lining or stomach ulcers that can become serious and may lead to bleeding, liver problems, serious kidney problems, severe increase in blood pressure, confusion, seeing, feeling or hearing things that are not there (hallucinations).

Not known: Yellowing of the skin and eyes (jaundice), liver failure, inflammation of the pancreas, fast heart rate, irregular heart rhythm (arrhythmia), restlessness, inflammation of the blood vessels.

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

Overdose:

You should never take more tablets than the doctor recommends.

If you do take too many Etoricoxib tablets, you should seek medical attention immediately.

Pharmacological Properties:

Pharmacodynamic Properties

Torix (Etoricoxib) is an oral, selective cyclo-oxygenase-2 (COX-2) inhibitor within the clinical dose range. Across clinical pharmacology studies, Etoricoxib produced dose-dependent inhibition of COX-2 without inhibition of COX-1 at doses up to 150 mg daily. Etoricoxib did not inhibit gastric prostaglandin synthesis and had no effect on platelet function.

Pharmacokinetic Properties

Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Etoricoxib is approximately 92% bound to human plasma protein over the range of concentrations of 0.05 to 5 µg/ml. Etoricoxib is extensively metabolised with <1% of a dose recovered in urine as the parent drug. Elimination of etoricoxib occurs almost exclusively through metabolism followed by renal excretion.

Special precautions for storage:

Store below 30°C.

Oct., 2018

I-Torix-TRX-EXO-R1/AE

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of the reach of children.

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