

1.6.3 PATIENT INFORMATION LEAFLET (PIL)

TORICOX - 120 (Etoricoxib Tablets 120 mg).

Brand Names: TORICOX - 120

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 pharmacist.
- This medicine has been prescribed for you. Do 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.

In this leaflet:

1. What **TORICOX - 120** is and what they are used for
2. Before you take **TORICOX - 120**
3. How to take **TORICOX - 120**
4. Possible side effects
5. How to store **TORICOX - 120**
6. Further information

1. What **TORICOX - 120** is and what they are used for

What is TORICOX - 120?

- **TORICOX - 120** contains the active substance etoricoxib. **TORICOX - 120** is one of a group of medicines called selective COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

What is TORICOX - 120 used for?

TORICOX-120 is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Also for the short-term treatment of moderate pain associated with dental surgery.

What is osteoarthritis?

Osteoarthritis is a disease of the joints. It results from the gradual breakdown of cartilage that cushions the ends of the bones. This causes swelling (inflammation), pain, tenderness, stiffness and disability.

What is rheumatoid arthritis?

Rheumatoid arthritis is a long term inflammatory disease of the joints. It causes pain, stiffness, swelling, and increasing loss of movement in the joints it affects. It may also cause inflammation in other areas of the body.

What is gout?

Gout is a disease of sudden, recurring attacks of very painful inflammation and redness in the joints. It is caused by deposits of mineral crystals in the joint.

What is ankylosing spondylitis?

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

2. Before you take TORICOX – 120.

Do not take TORICOX – 120

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of this medicine
- 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 disease
- if you have serious kidney disease
- if you are or could be pregnant or are breast-feeding (see ‘Pregnancy, breast feeding, and fertility’)
- if you are under 16 years of age
- if you have inflammatory bowel disease, such as Crohn’s Disease, Ulcerative Colitis, or Colitis
- if you have high blood pressure that has not been controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is adequately controlled)
- if your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain)
- if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)
- if you have had 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 think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking TORICOX-120 if:

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- You have a history of stomach bleeding or ulcers.
- You are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- 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. TORICOX-120 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. TORICOX-120 can mask or hide a fever, which is a sign of infection.
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.
- You are a woman trying to become pregnant.
- You are over 65 years of age.

If you are not sure if any of the above apply to you, talk to your doctor before taking TORICOX-120 to see if this medicine is suitable for you.

TORICOX-120 works equally well in older and younger adult patients. If you are over 65 years of age, your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for patients over 65 years of age.

Children and adolescents

Do not give this medicine to children and adolescents under 16 years of age.

Other medicines and TORICOX-120

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 TORICOX-120:

- 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)
- ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- lithium (a medicine used to treat some types of depression)
- 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
- diuretics (water tablets)
- 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)

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- birth control pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- aspirin, the risk of stomach ulcers is greater if you take TORICOX-120 with aspirin.

-aspirin for prevention of heart attacks or stroke:

TORICOX-120 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

-aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs):

do not take high dose aspirin or other anti-inflammatory medicines while taking TORICOX-120.

TORICOX-120 with food and drink

The onset of the effect of TORICOX-120 may be faster when taken without food. **Pregnancy, breast-feeding, and fertility**

Pregnancy

TORICOX-120 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.

Breast-feeding

It is not known if TORICOX-120 is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking TORICOX-120. If you are using TORICOX-120, you must not breast-feed.

Fertility

TORICOX-120 is not recommended in women attempting to become pregnant.

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking TORICOX-120.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness. **TORICOX-120 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.

3. How to take TORICOX – 120?

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. 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 TORICOX-120 for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

4. Possible side effects

Infections and infestations: alveolar osteitis

Metabolism and nutrition disorders: oedema/fluid retention

Nervous system disorders: dizziness, headache

Vascular disorders: hypertension.

Respiratory, thoracic and mediastinal disorders: bronchospasm

Gastrointestinal disorders: abdominal pain, Constipation, flatulence, gastritis, heartburn/acid reflux, diarrhea, dyspepsia / epigastric discomfort, nausea, vomiting, oesophagitis, oral ulcer.

5. How to store TORICOX – 120?

Store below 30⁰ C in dry & dark place. 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 carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What TORICOX – 120 (Etoricoxib Tablets 120 mg) contain,

The active substance is Etoricoxib. Each film coated tablet contains 120 mg of Etoricoxib.

The inactive ingredients in the tablets are Microcrystalline Cellulose BP, Lactose Monohydrate BP, Betadex BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Povidone K-30 BP, Purified Water BP, Purified Talc BP, Magnesium Stearate BP, Crospovidone BP, Hypromellose BP, Isopropyl Alcohol BP, Dichloromethane BP, Titanium Dioxide (Color Code Index:77891) BP, Macrogol 6000 (Polyethylene Glycol 6000) BP, Diethyl phthalate BP & Colour Quinoline Yellow Lake (Color Code Index: 15985) IHS.

7. What TORICOX – 120 (Etoricoxib Tablets 120 mg) Tablets look like and contents of the pack

TORICOX – 120 (Etoricoxib Tablets 120 mg) are A yellow coloured, circular, biconvex, film coated tablet, having plain on both sides.

10 Tablet in Alu/ Clear PVDC Blister & 3 such Blisters in a carton = 3 x 10's = 30 Tablet's.

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ochoa Laboratories

430, Mzz. F, Gundecha Indl. Complex

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Manufacturer

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TORICOX - 120
(Etoricoxib Tablets 120 mg)

Module 1



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