

Patient package insert in accordance with the Pharmacists' Regulations - 1986

The dispensing of this medicine requires a doctor's prescription

**Etoricoxib
Taro 30 mg**

**Etoricoxib
Taro 60 mg**

**Etoricoxib Taro
90 mg**

**Etoricoxib
Taro 120 mg**

**Film-coated
tablets**

**Film-coated
tablets**

**Film-coated
tablets**

**Film-coated
tablets**

Each tablet contains:

Each tablet contains:

Each tablet contains:

Each tablet contains:

etoricoxib 30 mg

etoricoxib 60 mg

etoricoxib 90 mg

etoricoxib 120 mg

Inactive ingredients and allergens: Please see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before using this medicine.

- This leaflet contains concise information about Etoricoxib Taro. If you have any further questions, 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 it seems to you that their condition is similar to yours.
- This medicine is not intended for children and adolescents under 16 years old.

1. What is Etoricoxib Taro and what is it used for?

1.1. What is Etoricoxib Taro?

Therapeutic group: This medicine belongs to a group of medicines called selective COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

1.2. What is this medicine used for?

Etoricoxib Taro 30 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis.

Etoricoxib Taro 60 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis.

Etoricoxib Taro 90 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from rheumatoid arthritis and ankylosing spondylitis.

Etoricoxib Taro 90 mg is also used for short term treatment of moderate pain after dental surgery.

Etoricoxib Taro 120 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from gout.

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 joints.

What is ankylosing spondylitis?

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

2. Before using this medicine**2.1. Do not use this medicine if:**

- You are allergic (hypersensitive) to etoricoxib or any of the other ingredients that this medicine contains (see section 6).
- You are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see section 4, "Side Effects").
- You have an active stomach ulcer or bleeding in your stomach or intestines.
- You have a serious liver disease.
- You have a serious kidney disease.
- You are or could be pregnant, or if you are breastfeeding (see section 2 "Pregnancy, breastfeeding, and fertility").
- You are under 16 years old.
- You have an inflammatory bowel disease, such as Crohn's disease, ulcerative colitis, or colitis.
- 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).
- You have heart problems including heart failure (moderate or severe), angina (chest pain).
- You have ischemic heart disease, have had a heart attack, bypass surgery, or peripheral vascular disease (poor circulation in the legs or feet due to narrowed or blocked blood vessels).
- You have had any kind of stroke (including mini-stroke, transient ischemic attack (TIA)).
Etoricoxib may slightly increase your risk of heart attack and stroke so patients who have previously had heart problems or stroke must not take it.

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

2.2. Special warnings regarding use of this medicine

Talk to your doctor or pharmacist before taking Etoricoxib Taro if:

- 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 heart disease.
- You have a history of high blood pressure. Etoricoxib Taro 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 a history of liver or kidney disease.
- You are being treated for an infection. Etoricoxib Taro can mask or hide a fever which is a sign of infection.
- You have diabetes, high cholesterol, or are a smoker. These factors can increase your risk of heart disease.
- You are a woman trying to become pregnant.
- You are over 65 years old.

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

Etoricoxib Taro works equally well in older and younger adult patients. If you are over 65 years old, your doctor will want to monitor you appropriately. No dosage adjustment is necessary for patients over 65 years old.

2.3. Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

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

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a medicine used to suppress the immune system, and often used to treat rheumatoid arthritis)
- cyclosporine or tacrolimus (medicines used to suppress the immune system)
- lithium (a medicine used to treat various types of depression)
- medicines used to treat high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, for example, enalapril, ramipril, losartan, and valsartan
- diuretics
- 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 (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 Etoricoxib Taro with aspirin.
 - Aspirin for prevention of heart attacks or stroke:
Etoricoxib Taro can be taken with **low-dose** aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke, do 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 Etoricoxib Taro.

2.4. Using this medicine and food

Etoricoxib Taro tablets may be taken with or without food. The onset of the effect of Etoricoxib Taro may be faster when it is taken without food.

2.5. Pregnancy, breastfeeding, and fertility

Pregnancy

Do not take Etoricoxib Taro 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 not sure or if you need more advice.

Breastfeeding

It is not known if Etoricoxib Taro passes into breast milk. If you are breastfeeding, or planning to breastfeed, consult your doctor before taking this medicine. If you are using Etoricoxib Taro, you must not breastfeed.

Fertility

Etoricoxib Taro is not recommended in women attempting to become pregnant.

2.6. Driving and using machines

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

Do not drive if you feel dizzy or sleepy.

Do not use any tools or machines if you feel dizzy or sleepy.

2.7. Important information about some of this medicine's ingredients

Etoricoxib Taro contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, tell your doctor before taking this medicine.

2.8. Children and adolescents

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

3. How to use this medicine?

Always take Etoricoxib Taro exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Only your doctor will determine your dose and how you should take the medicine.

Do not take more than the dose recommended 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 that you do not take Etoricoxib Taro for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

There are different strengths available for this medicine and depending on your condition your doctor will prescribe the tablet strength that is appropriate for you.

The usually recommended dose is:

Osteoarthritis

The recommended dose is 30 mg once a day; can be increased to a maximum of 60 mg once a day, if needed.

Rheumatoid arthritis

The recommended dose is 60 mg once a day; can be increased to a maximum of 90 mg once a day, if needed.

Ankylosing spondylitis

The recommended dose is 60 mg once a day; can be increased to a maximum of 90 mg once a day, if needed.

In cases of acute arthritic gout and pain after dental surgery, use Etoricoxib Taro only for the symptomatic 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 a day, limited to a maximum of 3 days treatment.

Patients with liver problems

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

Do not exceed the recommended dose.

Use in children and adolescents

Do not give Etoricoxib Taro to children or adolescents under 16 years old.

Elderly

No dose adjustment is necessary for elderly patients. As with other medicines, caution should be exercised in elderly patients.

Method of administration

Etoricoxib Taro is for oral use. Take the tablets once a day. Etoricoxib Taro tablets may be taken with or without food. Swallow the medicine with a small amount of water. No information is available about crushing/splitting/chewing the tablets.

If you take more Etoricoxib Taro than you should

Never take more tablets than your doctor recommends. If you take too many Etoricoxib Taro tablets, seek medical attention immediately. If you have taken an overdose, or if a child has accidentally swallowed some medicine, proceed immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take Etoricoxib Taro

It is important to take Etoricoxib Taro exactly as your doctor has prescribed it. If you miss a dose, take the next tablet at the usual time on the following day. Do not take a double dose to make up for a missed dose.

Complete the full course of treatment as your doctor has recommended.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, Etoricoxib Taro may cause side effects in some users. Do not be alarmed by this list of side effects, you may not experience any of them.

If you develop any of the following signs, stop taking Etoricoxib Taro and consult your doctor immediately (see section 2, “Before using this medicine”):

- shortness of breath, chest pain, and swollen ankles appear or get worse
- yellowing of the skin and eyes (jaundice) - these are signs of liver problems
- severe or continual stomach pain or your stools are black
- an allergic reaction which can include skin reactions such as ulcers or blisters, or swelling of the face, lips, tongue, or throat which may cause difficulty breathing

Other side effects that may occur during treatment with Etoricoxib Taro:

Very common side effects – affect more than one in 10 users

- stomach pain

Common side effects – affect 1-10 in 100 users

- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (edema)
- dizziness, headache
- palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia)
- increased blood pressure
- wheezing or shortness of breath (bronchospasms)
- constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhea, indigestion (dyspepsia)/ stomach discomfort, nausea, vomiting, inflammation of the esophagus, mouth ulcers
- changes in blood tests related to your liver
- bruising
- weakness and fatigue, flu-like illness

Uncommon side effects – affect 1-10 in 1,000 users

- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection
- changes in laboratory values (decreased number of red blood cells, decreased number of white blood cells, decreased platelets)
- hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
- appetite increases or decreases, weight gain
- anxiety, depression, decreased mental sharpness: seeing, feeling or hearing things that are not there (hallucinations)
- taste alteration, inability to sleep, numbness or tingling, sleepiness
- blurred vision, eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure, or heaviness in the chest (angina pectoris), heart attack
- flushing, stroke, mini-stroke (transient ischemic attack), severe increase in blood pressure, inflammation of the blood vessels

- cough, shortness of breath, nose bleed
- stomach or bowel bloating, changes in your bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, irritable bowel syndrome, inflammation of the pancreas
- swelling of the face, skin rash or itchy skin, redness of the skin
- muscle cramp/spasm, muscle pain/stiffness
- high levels of potassium in your blood, changes in blood or urine tests relating to your kidneys, serious kidney problems
- chest pain

Rare side effects – affect more than 1 user in 10,000

- angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing, and may be serious enough to require immediate medical attention) / anaphylactic reactions including shock (a serious allergic reaction that requires immediate medical attention)
- confusion, restlessness
- liver problems (hepatitis)
- low levels of sodium in your blood
- liver failure, yellowing of the skin and/or eyes (jaundice)
- serious skin reactions

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use Etoricoxib Taro after the expiry date (exp. date) that is stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Store below 25°C.

Store in the original package to protect from moisture.

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. Additional information

- In addition to the active ingredient this medicine also contains:

Core:

calcium hydrogen phosphate, microcrystalline cellulose, magnesium stearate, croscarmellose sodium.

Tablet coating:

hypromellose, titanium dioxide, triacetin, lactose monohydrate.

What Etoricoxib Taro looks like and what the package contains

Etoricoxib Taro tablets are available in four strengths:

- **Etoricoxib Taro 30 mg** are white, round, bi-convex, film-coated tablets marked "E9OX" on one side and "30" on the other side.
- **Etoricoxib Taro 60 mg** are white, round, bi-convex, film-coated tablets marked "E9OX" on one side and "60" on the other side.
- **Etoricoxib Taro 90 mg** are white, round, bi-convex, film-coated tablets marked "E9OX" on one side and "90" on the other side.
- **Etoricoxib Taro 120 mg** are white, round, bi-convex, film-coated tablets marked "E9OX" on one side and "120" on the other side.

Pack sizes:

30 mg: packages of 28 tablets in blisters.

60, 90 mg: packages of 14 tablets in blisters.

120 mg: packages of 7 tablets in blisters.

Manufacturer:

Synthon Hispania, S.L., C/ Castelló no1, Pol. Las Salinas, Sant Boi de Llobregat, 08830 Barcelona, Spain

Registration holder's name and address:

Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Etoricoxib Taro 30 mg tablets: 160-49-34822-00

Etoricoxib Taro 60 mg tablets: 160-50-34823-00

Etoricoxib Taro 90 mg tablets: 160-51-34824-00

Etoricoxib Taro 120 mg tablets: 160-52-34825-00