

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) 1986

This medicine can be sold under doctor's prescription only

ETORICOXIB-TRIMA 30 mg Tablets	ETORICOXIB-TRIMA 60 mg Tablets	ETORICOXIB-TRIMA 90 mg Tablets	ETORICOXIB-TRIMA 120 mg Tablets
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Each tablet contains:
etoricoxib 30 mg | etoricoxib 60 mg | etoricoxib 90 mg | etoricoxib 120 mg

For a list of inactive ingredients please refer to section 6.

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **ETORICOXIB-TRIMA**. 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 their ailment seems similar to yours.
- This medicine is not intended for children and adolescents under 16 years of age.

1. WHAT ETORICOXIB-TRIMA IS AND WHAT IT IS USED FOR
ETORICOXIB-TRIMA 30 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis.

ETORICOXIB-TRIMA 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-TRIMA 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-TRIMA 90 mg** is also used for the short term treatment of moderate pain after dental surgery.

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

Therapeutic group: **ETORICOXIB-TRIMA** 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).

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 ETORICOXIB-TRIMA
Do not use this medicine if you:

- are allergic (hypersensitive) to etoricoxib or any of the other ingredients of this medicine (detailed in section 6).
- are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see "Side Effects", section 4).
- have a current stomach ulcer or bleeding in your stomach or intestines.
- have serious liver disease.
- have serious kidney disease.
- are or could be pregnant or if you are breast-feeding (see "Pregnancy, breast feeding, and fertility", section 2).
- are under 16 years of age.
- have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis.
- 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 suffer from heart failure (moderate or severe).
- you suffer from ischemic heart disease, or peripheral vascular disease (poor circulation in the legs or feet due to narrowing or blocked arteries).
- you have had any kind of stroke (including mini-stroke, transient ischaemic attack (TIA)). Etoricoxib may slightly increase your risk of heart attack and stroke and this is why it should not be used by patients 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.

Special warnings and use of ETORICOXIB-TRIMA
Talk to your doctor or pharmacist before taking **ETORICOXIB-TRIMA** if:

- 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. **ETORICOXIB-TRIMA** 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-TRIMA** 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 ETORICOXIB-TRIMA** to see if this medicine is suitable for you.

ETORICOXIB-TRIMA 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.

Taking other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.
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-TRIMA**:

- 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, ramipril, 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)
- 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-TRIMA** with aspirin.
 - aspirin for prevention of heart attacks or stroke.

ETORICOXIB-TRIMA 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 **ETORICOXIB-TRIMA**.

Taking ETORICOXIB-TRIMA with food and drink
ETORICOXIB-TRIMA tablets may be taken with or without food. The onset of the effect of **ETORICOXIB-TRIMA** may be faster when taken without food.

Pregnancy, breast-feeding and fertility
Pregnancy
ETORICOXIB-TRIMA 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 **ETORICOXIB-TRIMA** is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking **ETORICOXIB-TRIMA**. If you are using **ETORICOXIB-TRIMA**, you must not breast-feed.

Fertility
ETORICOXIB-TRIMA is not recommended in women attempting to become pregnant.
Driving and using machines
Dizziness and sleepiness have been reported in some patients taking **ETORICOXIB-TRIMA**. Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.
Children and adolescents
Do not give this medicine to children and adolescents under 16 years of age.

3. HOW TO USE ETORICOXIB-TRIMA?
Always take **ETORICOXIB-TRIMA** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dosage and treatment will only be determined by physician.
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 you should not take **ETORICOXIB-TRIMA** 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 medicinal product and depending on your disease 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, increased to a maximum of 60 mg once a day if needed.
Rheumatoid arthritis
The recommended dose is 60 mg once a day, increased to a maximum of 90 mg once a day if needed.

Ankylosing spondylitis
The recommended dose is 60 mg once a day, increased to a maximum of 90 mg once a day if needed.
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.

Do not exceed the recommended dose.
Use in children and adolescents
ETORICOXIB-TRIMA should not be given to children or adolescents under 16 years of age.

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

Method of administration
ETORICOXIB-TRIMA is for oral use. Take the tablets once a day. **ETORICOXIB-TRIMA** can be taken with or without food.
Swallow the medicine with a small amount of water.

As there is no score line, do not split the tablets. No information is available about crushing/chewing.
If you take more ETORICOXIB-TRIMA than you should
You should never take more tablets than the doctor recommends. If you do take too many **ETORICOXIB-TRIMA** tablets, you should seek medical attention immediately.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
If you forgot to take ETORICOXIB-TRIMA
It is important to take **ETORICOXIB-TRIMA** as your doctor has prescribed.

If you forget to take your medicine at the proper time, do not take a double dose. Take the next dose on the following day at the usual time, and consult your doctor.
Adhere to the treatment as recommended by your doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine before 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 on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS
Like all medicines, **ETORICOXIB-TRIMA** can cause side effects in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.
If you develop any of these signs you should stop ETORICOXIB-TRIMA and talk to your doctor immediately (see "Before you take ETORICOXIB-TRIMA", section 2):

- shortness of breath, chest pains, or ankle swelling appear 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-TRIMA**:
Very common side effects (affect more than 1 user in 10)
 - 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 (oedema)
 - 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, diarrhoea, indigestion (dyspepsia)/stomach discomfort, nausea, being sick (vomiting), inflammation of the oesophagus, 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, platelets decreased)
 - hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
 - appetite increases or decreases, weight gain
 - anxiety, depression, decreases in 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 ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels
 - cough, breathlessness, 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 kidney, serious kidney problems
 - chest pain

- Rare side effects** (affect 1-10 in 10,000 users):
 - angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, and may be serious enough to require immediate medical attention)/anaphylactic/anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention)
 - confusion, restlessness
 - liver problems (hepatitis)
 - low blood levels of sodium
 - liver failure, yellowing of the skin and/or eyes (jaundice)
 - severe skin reactions

If a side effect appears, if any of the side effects gets serious or if you notice a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@mo.gov.il>

You can also report side effects by email to: safety@trima.co.il
5. HOW TO STORE ETORICOXIB-TRIMA?
Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the

reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
Do not use **ETORICOXIB-TRIMA** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.
Store in a dry place, below 25°C.

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. FURTHER INFORMATION
What ETORICOXIB-TRIMA contains

- The active substance is etoricoxib. Each film-coated tablet contains 30, 60, 90 or 120 mg of etoricoxib.
- The other ingredients are:

ETORICOXIB-TRIMA 30:
Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone, croscarmellose sodium, magnesium stearate, hydroxypropylmethyl cellulose (HPMC), titanium dioxide, polyethylene glycol.

ETORICOXIB-TRIMA 60:
Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone, croscarmellose sodium, magnesium stearate, hydroxypropylmethyl cellulose (HPMC), titanium dioxide, polyethylene glycol, brilliant Blue FCF.

ETORICOXIB-TRIMA 90:
Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone, croscarmellose sodium, magnesium stearate, hydroxypropylmethyl cellulose (HPMC), titanium dioxide, polyethylene glycol, brilliant Blue FCF.

ETORICOXIB-TRIMA 120:
Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone, croscarmellose sodium, magnesium stearate, hydroxypropylmethyl cellulose (HPMC), titanium dioxide, polyethylene glycol, brilliant Blue FCF.

What ETORICOXIB-TRIMA looks like and contents of the pack
ETORICOXIB-TRIMA tablets are available in four strengths:
ETORICOXIB-TRIMA 30 mg tablets are round, biconvex, white film coated tablet.
ETORICOXIB-TRIMA 60 mg tablets are round, biconvex, pale blue film coated tablet.
ETORICOXIB-TRIMA 90 mg tablets are round, biconvex, white film coated tablet.
ETORICOXIB-TRIMA 120 mg tablets round, biconvex, pale blue film coated tablet.

Pack sizes:
Tablets are packaged in blisters of 7, 10, 14, 28 or 30 tablets. Not all pack sizes may be marketed.
Manufacturer and marketing authorization holder:
Trima, Israeli Pharmaceuticals Maabarot Ltd., Maabarot 4023000, Israel.

This patient leaflet was formatted according to Ministry of Health guidelines and was reviewed and approved by the Ministry of Health in June 2018.

Drug registration no. listed in the official registry of the Ministry of Health:
ETORICOXIB-TRIMA 30 mg tablets: 160-57-35211-00
ETORICOXIB-TRIMA 60 mg tablets: 160-58-35212-00
ETORICOXIB-TRIMA 90 mg tablets: 160-59-35181-00
ETORICOXIB-TRIMA 120 mg tablets: 160-60-35213-00

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