

SCHEDULING STATUS**S3****MARACOXIA 60** (film-coated tablet)**MARACOXIA 90** (film-coated tablet)**MARACOXIA 120** (film-coated tablet)

Etoricoxib 60 mg/90 mg/120 mg respectively per tablet

Contains sugar: Lactose monohydrate 1,680 mg, 2 520 mg and 3,360 mg respectively

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is
to say essentially 'sodium free'.

Read all of this leaflet carefully before you start taking MARACOXIA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MARACOXIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MARACOXIA is and what it is used for.
2. What you need to know before you take MARACOXIA.
3. How to take MARACOXIA.
4. Possible side effects.
5. How to store MARACOXIA.
6. Contents of the pack and other information.



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1. What MARACOXIA is and what it is used for

- The active ingredient etoricoxib belongs to a group of medicines called COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory medicines.
- Your doctor has prescribed MARACOXIA for one of the following conditions:
 - relief of symptoms of osteoarthritis,
 - relief of symptoms of rheumatoid arthritis,
 - treatment of ankylosing spondylitis,
 - short term relief of acute pain, treatment limited to a maximum period of 8 days,
 - treatment of moderate to severe acute pain after dental surgery,
 - treatment of menstrual pain,
 - treatment of acute gout attacks.

2. What you need to know before you take MARACOXIA

Do not take MARACOXIA:

- If you are hypersensitive (allergic) to the active substance etoricoxib or any of the other ingredients of MARACOXIA.
- If you are allergic to non-steroidal anti-inflammatory medicines, including aspirin and COX-2 inhibitors, such as MARACOXIA.
- If you have a stomach ulcer or bleeding in your stomach or intestines.
- If you have a serious liver disease.
- If you have a serious kidney disease.
- If you are pregnant or breastfeeding (*see 'Pregnancy and breastfeeding and fertility'*).
- Do not give to children or adolescents under 16 years of age as safety and efficacy have not been established.



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- If you have an inflammatory bowel disease.
- If your doctor has diagnosed heart problems including heart failure (moderate or severe), 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 ischaemic 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 or nurse if you are not sure whether your blood pressure is adequately controlled).
- If you are having heart bypass.
- If you are taking lithium (a medicine used to treat some types of depression).
- If you are taking digoxin (a medicine for heart failure and irregular heart rhythm).

Warnings and precautions

Take special care with MARACOXIA:

MARACOXIA may cause serious health conditions such as involving the heart, gastro-intestinal (stomach) or skin reactions which may be fatal.

- If you have a history of stomach bleeding or ulcers.
- If you are dehydrated due to loss of too much water from the body, for example by being sick, diarrhoea or sweating.
- If you have swelling due to fluid retention.
- If you have a history of heart failure or any other form of heart disease.



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- If you have a history of high blood pressure. MARACOXIA 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.
- If you have any history of liver or kidney disease.
- If you are being treated for an infection, MARACOXIA can mask or hide a fever, which is a sign of infection.
- If you are a woman trying to become pregnant.
- If you are elderly (i.e. over 65 years of age).
- If 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 MARACOXIA to find out if this medicine is suitable for you.

Codeine/ NSAIDs (as contained in MARCOXA) combinations contains codeine, which is an opioid medicine.

Repeated use of codeine/NSAIDs (as contained in MARCOXA) combinations may result in you becoming accustomed to it (needing to take higher doses). Repeated use of codeine/NSAIDs (as contained in MARCOXA) combinations may also lead to dependence, abuse and addiction, which may result in life-threatening overdose due to the codeine component.

If you are taking codeine/NSAIDs (as contained in MARCOXA) combinations for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (*see section 4*).

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If you experience any of the following signs whilst taking codeine/NSAIDs (as contained in MARCOXA) combinations, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this medicine for longer than advised.
- You need to take more than the recommended dose.
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'.
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine.
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects').

Other medicines and MARACOXIA:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Medicines that thin your blood (anticoagulants), such as warfarin.
- Rifampicin (an antibiotic).
- Methotrexate (a medicine 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.
- Lithium (a medicine used to treat some types of depression) (*see 'Do not take MARACOXIA'*).
- Diuretics (water tablets).
- Ciclosporin and tacrolimus (medicines used for suppressing the immune system).

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- Digoxin (a medicine for heart failure and irregular heart rhythm) (*see ‘Do not take MARACOXAXA’*).
- Minoxidil (a medicine 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 MARACOXAXA with aspirin.
- Do not take high dose aspirin or other anti-inflammatory medicines while you are taking MARACOXAXA.
- If you are taking low dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor.
- If you are taking medicines called furosemide and thiazides.

Remember to tell your doctor if you start taking any other medicines while you are receiving MARACOXAXA.

MARACOXAXA with food and drink and alcohol:

MARACOXAXA can be taken with or without food.

Pregnancy and breastfeeding and fertility

MARACOXAXA should not be taken during pregnancy. If you think you could be pregnant, or if you are planning to become pregnant, stop taking the tablets and consult your doctor.

It is not known if MARACOXAXA is excreted in human milk. If you are using MARACOXAXA, you must not breastfeed.

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If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MARACOXIA.

Driving and using machinery:

It is not always possible to predict to what extent MARACOXIA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MARACOXIA affects them.

- Dizziness and sleepiness have been reported in some patients taking etoricoxib, as in MARACOXIA.
- Do not drive if you experience dizziness or sleepiness.
- Do not use any tools or machines if you experience dizziness or sleepiness.

Important information about some of the ingredients of MARACOXIA:

- MARACOXIA contains lactose, a type of sugar, which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars) talk to your doctor before taking MARACOXIA tablets.
- This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium free'.

3. How to take MARACOXIA:

Do not share medicines prescribed for you with any other person.

Always take MARACOXIA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Do not take more than the recommended dose for your condition.



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- 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 MARACOXIA for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.
- MARACOXIA tablets should not be taken by children or adolescents under 16 years of age.
- Take MARACOXIA tablets once a daily by mouth.
- MARACOXIA can be taken with or without food.
- Your doctor will decide what dose of MARACOXIA you should take and how long you should take it.
- If you have the impression that the effect of MARACOXIA is too strong or too weak, tell your doctor or pharmacist.

The usual dose is:

For relief of symptoms of osteoarthritis:

- The recommended dose is 60 mg once daily.

For relief of symptoms for rheumatoid arthritis:

- The recommended dose is 90 mg once a day

For the treatment of ankylosing spondylitis:

- The recommended dose is 90 mg once a day.

Acute pain conditions:

- The recommended dose is 90 or 120 mg once daily, limited to a maximum of 8 days treatment.

For the relief of gout attacks:

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- 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.

For 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 relief of pain after dental surgery:

- The recommended dose is 90 mg once daily.

If you take more MARACOXIA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MARACOXIA:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

MARACOXIA can have side effects:

Not all side effects reported for MARACOXIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MARACOXIA, please consult your doctor, pharmacist or healthcare professional for advice.

If any of the following happens, stop taking MARACOXIA and call your doctor immediately or go to the casualty department at your nearest hospital:

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- An allergic reaction - which can include skin problems such as ulcers or blistering, swelling of the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing.
- Shortness of breath, chest pains, or ankle swelling appear or if they get worse.
- Codeine/NSAIDs (as contained in MARCOXA) combinations, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (*see section 2*). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MARACOXIA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin and eyes (jaundice) – these are signs of liver disorders.
- Severe or continual stomach pain or your stools become black.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Stomach pain;
- swelling of the legs and/or feet due to fluid retention (oedema);
- dizziness, headache;



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- palpitations (fast or irregular heartbeat);
- wheezing or shortness of breath (bronchospasms);
- 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;
- weakness and fatigue, flu-like illness.

The following side effects have been reported less frequently:

- Gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection;
- 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);
- irregular heart rhythm (dysrhythmia);
- constipation, appetite increases or decreases, weight gain;
- anxiety, depression, decreases in mental sharpness; confusion; 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;



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- cough, breathlessness, nose bleed;
- stomach or bowel bloating, vomiting, 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 disorders;
- chest pain;
- angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, which 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.

The following side effects have been reported but the frequency is unknown:

- Increased blood pressure;
- irregular heart rhythm (dysrhythmia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or healthcare professional.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of MARACOXIA.

5. How to store MARACOXIA

Store at or below 30 °C.

Blisters: Store in the original package in order to protect from moisture and keep in the carton until required for use.

Bottles: Keep the container tightly closed in order to protect from moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not store in a bathroom.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What MARACOXIA contains:

The active substance is etoricoxib.

The other ingredients are:

MARACOXIA 60:

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Core: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, silica colloidal anhydrous, {coating: Opadry II green 31K510020 (composition: HPMC hypromellose (15cP), lactose monohydrate, titanium dioxide, triacetin, iron oxide yellow, FD&C blue #2/indigo carmine aluminium lake (dye strength (11 %-14 %), carnuba wax))}.

MARACOXIA 90:

Core: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, silica colloidal anhydrous, Coating: Opadry II white 31K580000 (composition: HPMC hypromellose (15cP), lactose monohydrate, titanium dioxide, triacetin, carnuba wax)}.

MARACOXIA 120:

Core: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, silica colloidal anhydrous, Coating: Opadry II green 31K510019 (composition: HPMC hypromellose (15cP), lactose monohydrate, titanium dioxide, triacetin, FD&C blue #2/indigo carmine, aluminium lake (dye strength (3 %-5 %), iron oxide yellow, carnuba wax))

What MARACOXIA looks like and contents of the pack:

What MARACOXIA looks like:

MARACOXIA 60:

A green film-coated, round, biconvex, bevelled edge tablet debossed with “E” on one side and “60” on the other side.

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MARACOXIA 90:

A white film-coated, round, biconvex, bevelled edge tablet debossed with “E” on one side and “90” on the other side.

MARACOXIA 120:

A pale green film-coated, round, biconvex, bevelled edge tablet debossed with “E” on one side and “120” on the other side.

Contents of the pack:

Cold form blister pack comprises of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on other side i.e. OPA/Al/PVC) on one side and hard tempered aluminum foil (coated with VMCH heat seal lacquer) on the other side.

Suitable number of blister strips will be placed in an outer cardboard carton. The number of tablets per strip and the number of strips in carton shall be based on commercial requirement.

PVC/PVdC blister pack comprises of clear, transparent PVC laminated with PVdC on one side and hard tempered aluminium foil coated with heat seal lacquer on other side (PVdC/PVC/Al). Heat seal lacquer contains 86 % Vinyl Chloride, 13 % Vinyl Acetate & 1 % maleic acid.

Suitable number of blister strips will be placed in an outer cardboard carton. The number of tablets per strip and the number of strips in each carton shall be based on commercial requirement.

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HDPE bottle pack comprises of round wide mouth white high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) screw closure with induction sealing liner along with wad.

The HDPE bottle pack may either be placed in an outer cardboard carton or provided without a carton based on commercial requirement.

Pack sizes:

60 mg: 28's, 30's

90 mg: 7's, 28's, 30's

120 mg: 7's, 28's, 30's

Not all pack sizes may be marketed.

Registration numbers/reference numbers

MARACOXIA 60: 49/3.1/0588

MARACOXIA 90: 49/3.1/0589

MARACOXIA 120: 49/3.1/0590

Holder of Certificate of Registration and Manufacturer

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