SCHEDULING STATUS

S3

ADCO ETORICOXIB 30 mg, film coated tablets

ADCO ETORICOXIB 60 mg, film coated tablets

ADCO ETORICOXIB 90 mg, film coated tablets

ADCO ETORICOXIB 120 mg, film coated tablets

Etoricoxib

Sugar free

Read all of this leaflet carefully before you start taking ADCO ETORICOXIB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADCO ETORICOXIB 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 ADCO ETORICOXIB is and what it is used for
2. What you need to know before you take ADCO ETORICOXIB
3. How to take ADCO ETORICOXIB
4. Possible side effects

5. How to store ADCO ETORICOXIB
6. Contents of the pack and other information

1. What ADCO ETORICOXIB is and what it is used for

The active substance is:

Etoricoxib 30 mg/ 60mg/ 90 mg or 120 mg.

ADCO ETORICOXIB 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). ADCO ETORICOXIB is used to help reduce the pain and swelling (inflammation) in the joints and muscles of people with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout. It is also used for the short-term treatment of moderate pain including cramp-like pain or discomfort before or during a menstrual period, and pain associated with minor dental procedures.

2. What you need to know before you take ADCO ETORICOXIB

Do not take ADCO ETORICOXIB

- If you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of ADCO ETORICOXIB (see section 6).
- If you have taken aspirin or other anti-inflammatory medicine (commonly known as NSAIDs) before, which caused asthma, itchy swellings on the skin (hives), runny nose, or other allergic reactions.
- If you have a current stomach ulcer or bleeding in your stomach or intestines.
- If you have had gastro-intestinal (stomach or duodenal) ulcers.

- If you have had bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces) after you have taken other NSAIDs.
- If you have serious liver disease.
- If you have serious kidney disease or kidney failure.
- If you are or could be pregnant or are breastfeeding (see section 2).
- If you are under 16 years of age.
- If you have inflammatory bowel disease.
- 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 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 had or are having major surgery on your heart or arteries.
- 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 currently using digoxin (medicines used to treat heart failure) or lithium (medicines used to treat mental disorders).
- If you are using medications containing sulphonamides (antibiotics used to treat bacterial infection).

Warnings and precautions

Take special care with ADCO ETORICOXIB:

- If you have a history of kidney disease.

- If you have a history of liver disease, your liver function should continuously be assessed.
- If you have a history of asthma, hives, itching or skin rash.
- If you are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- If you have a history of heart failure, heart attack or any other form of heart disease.
- If you have a history of high blood pressure.
- If you have swelling of the ankles, feet or legs due to fluid retention (also called oedema).
- If you have narrow or blocked arteries of the extremities.
- If you have a history of stroke or mini stroke.
- If you have conditions which increase your risk of heart disease such as diabetes, high cholesterol, smoking or a first degree relative with heart disease.
- If you are using higher doses of ADCO ETORICOXIB and at longer periods, as you may be at risk to experience heart problems.
- If you are currently taking low-dose aspirin for the prevention of heart attack or stroke, as you may experience more gastrointestinal adverse reactions.
- If you have a history of ulcers or bleeding in your stomach or intestines including inflammatory bowel diseases such as Crohn’s disease or ulcerative colitis, gastro-oesophageal reflux diseases or angiodysplasia (an abnormality with blood vessels of the gastrointestinal tract).
- If you are using ADCO ETORICOXIB more frequently or in higher than normal quantities, you may be at an increased risk of experiencing gastrointestinal problems.
- If you are experiencing serious gastrointestinal problems (such as bleeding from the gastrointestinal tract), stop using ADCO ETORICOXIB.
- If you have an infection. ADCO ETORICOXIB can mask or hide a fever, which is a sign of infection.

- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- If you are elderly (i.e. over 65 years of age).
- If you are an elderly person, as you may have a higher possibility to experience unwanted effects (such as gastrointestinal problems and bleeding which may be life threatening) whilst using ADCO ETORICOXIB.

Adverse experiences can occur at a higher incidence in older patients compared to younger patients. If you are elderly (i.e. over 65 years of age), your doctor may want to appropriately keep a check on you.

Children and adolescents

Do not give ADCO ETORICOXIB to children and adolescents under 16 years of age.

Other medicines and ADCO ETORICOXIB

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Your doctor may want to check that your medicines are working properly if you are taking:

- Warfarin (a medicine used to prevent blood clots) and other blood thinning medicines (known as anticoagulants).
- Rifampicin (an antibiotic used to treat tuberculosis and other infections).
- Water pills (diuretics).
- ACE inhibitors and angiotensin receptor blockers, (medicines used to lower high blood pressure or treat heart failure).
- Lithium (a medicine used to treat mood swings and some types of depression).

- Ethinyl estradiol (hormone used in some birth control pills).
- Conjugated estrogens used in some hormone replacement therapy.
- Methotrexate (a medicine used to treat arthritis and some types of cancer.
- Ciclosporin or tacrolimus (medicines used for suppressing the immune system).
- Aspirin when used regularly for conditions other than to prevent heart attack or stroke. ADCO ETORICOXIB can be taken with low dose aspirin. If you are currently taking low dose aspirin for the prevention of a heart attack or stroke, you should continue to do so unless identified by your doctor. ADCO ETORICOXIB cannot replace aspirin for this purpose. Do not take high dose aspirin or other anti-inflammatory medicines while taking ADCO ETORICOXIB, as the use of two or more anti-inflammatory medicines may cause an increase in stomach or bowel side effects.
- Corticosteroids such as prednisone and cortisone (medicines that lowers inflammation in the body), increase the risk of gastrointestinal adverse reactions.
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used in the treatment of depression) and anti-platelet medicines (medicines that makes your blood less sticky), increases the risk of gastrointestinal bleeding.
- Digoxin (a medicine for heart failure and irregular heart rhythm).
- Minoxidil (a medicine used to treat high blood pressure).
- Salbutamol tablets or oral solution (a medicine for asthma).

ADCO ETORICOXIB with food and drink

ADCO ETORICOXIB may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

- ADCO ETORICOXIB should not be taken during pregnancy. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ADCO ETORICOXIB. Consult your doctor if you are unsure or need more advice.
- The use of ADCO ETORICOXIB is not recommended in woman attempting to conceive (fall pregnant).
- If you are breastfeeding, or planning to breastfeed, consult your doctor before taking ADCO ETORICOXIB. If you are using ADCO ETORICOXIB you must not breastfeed.

Driving and using machines

The effect of ADCO ETORICOXIB on the ability to drive a car or operate machinery has not been studied. Do not drive or use any tools or machinery if you experience dizziness or sleepiness.

It is not always possible to predict to what extent of ADCO ETORICOXIB 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 of ADCO ETORICOXIB affects them.

ADCO ETORICOXIB contains sodium

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 ADCO ETORICOXIB

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

Always take ADCO ETORICOXIB exactly as your doctor, or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Osteoarthritis: The recommended dose is 30 mg once daily. In some patients with insufficient relief from symptoms, the dose may be increased to 60 mg once daily.

Rheumatoid arthritis: The recommended dose is 90 mg once daily.

Ankylosing spondylitis: The recommended dose is 90 mg once daily.

Gout: The recommended dose is 120 mg once daily limited to a maximum of 8 days treatment.

Acute pain conditions: The recommended dose is 90 mg or 120 mg once daily limited to a maximum of 8 days treatment.

Menstrual pain: The recommended dose is 120 mg once daily.

Post-operative dental surgery pain: The recommended dose is 90 mg once daily.

Take ADCO ETORICOXIB tablets by mouth once a day. ADCO ETORICOXIB can be taken with or without food.

Your doctor will tell you how long your treatment with ADCO ETORICOXIB will last. If you have the impression that the effect of ADCO ETORICOXIB is too strong or too weak, tell your doctor or pharmacist.

Your doctor will decide on your dosages depending on your condition.

If you take more ADCO ETORICOXIB than you should

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

If you forget to take a dose of ADCO ETORICOXIB

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

It is important to take ADCO ETORICOXIB as your doctor has prescribed. If you miss a dose, resume your usual schedule the following day.

4. Possible side effects

ADCO ETORICOXIB can have side effects.

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

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

- An allergic reaction, including skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing or swallowing.

- Shortness of breath, chest pains, or ankle swelling appear or if they get worse (which may be a symptom of heart failure).
- Vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools), or bloody diarrhoea – these may be symptoms of bleeding stomach ulcers which may occur at any time during use and without warning.
- Fast or irregular heartbeats, also called palpitations (dysrhythmia).
- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome).
- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO ETORICOXIB. 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:

- Skin rash or itchiness.
- Pinkish, itchy swellings on the skin, also called hives or nettle rash.
- Redness of the skin.
- Severe stomach pain.
- Passing little or no urine.
- Yellowing of the skin and/or eyes, also called jaundice.
- A feeling of pain, tightness, pressure or heaviness in the chest (angina), heart attack.

- Increased tendency to bleed/bruise, or tendency to bleed for a longer period of time – these may be symptoms of reduced platelets in your body.
- Severe pain and swelling following a dental extraction, “dry socket”.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Swelling of the legs and/or feet due to fluid retention (oedema).
- Dizziness, headache.
- 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.
- Bleeding in the digestive tract (melaena or haematemesis).
- Mouth ulcers with sore breaks in the skin (ulcerative stomatitis).
- Lower gut disorders (inflammatory bowel disease or Crohn’s disease).
- Weakness and fatigue, flu-like illness.

Less frequent side effects:

- Gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/ stomach flu), upper respiratory infection, urinary tract infection.
- 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).
- Flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels.
- 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.
- Muscle cramp/spasm, muscle pain/stiffness.
- Confusion, restlessness.
- Changes in certain components of your blood.
- Formation of fluid-filled blisters or sacs.

Side effects of an unknown frequency:

- Cardiovascular effects such as high blood pressure and heart failure.
- Low blood counts (thrombocytopenia).
- Hypersensitivity reactions such as rapid swelling of the face (angioedema) or severe allergic reactions.
- Confusion, hallucinations.
- Mood changes (depression).
- Restlessness, sleeplessness.
- Loss of taste sensation, blurred vision.
- Heart failure, changes in heart rhythm and blood pressure.
- Difficulty breathing (bronchospasm).
- Stomach pain, vomiting, diarrhoea.

- Bleeding of the gastrointestinal tract.
- Mouth ulcers.
- Liver failure or yellowing of the skin (jaundice).
- Kidney failure or dysfunction.
- Skin reactions such as itching, rash, severe skin peeling and blistering.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction 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 ADCO ETORICOXIB.

5. How to store ADCO ETORICOXIB

Store all medicines out of reach of children.

Store at or below 25 ºC.

Store in the original package.

Do not use after the expiry date stated on the carton and blister.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ADCO ETORICOXIB contains

The active substance is:

Etoricoxib 30 mg/ 60 mg/ 90 mg or 120 mg.

The other ingredients for ADCO ETORICOXIB are:

Calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate (E470b), microcrystalline cellulose (E460).

ADCO ETORICOXIB 30 mg, 60 mg and 120 mg is coated with the following ingredients: Glycerol monostearate (E471), indigo carmine aluminium lake (E132), polyvinyl alcohol (E1203), sodium laurylsulfate, talc (E553b), titanium dioxide (E171), yellow iron oxide (E172).

ADCO ETORICOXIB 90 mg is coated with the following ingredients: Glycerol monostearate (E471), polyvinyl alcohol (E1203), sodium laurylsulfate, talc (E553b), titanium dioxide (E171).

What ADCO ETORICOXIB looks like and contents of the pack

ADCO ETORICOXIB 30 mg: Blue-green, apple-shaped, biconvex film coated tablet, debossed with “30” on one side and plain on the other, with dimensions of 5,8 x 5,9 mm ± 7,5 %.

ADCO ETORICOXIB 60 mg: Dark green, apple-shaped, biconvex film coated tablet, debossed with “60” on one side and plain on the other, with dimensions of 7,1 x 7,3 mm ± 7,5 %.

ADCO ETORICOXIB 90 mg: White, apple-shaped, biconvex film coated tablet, debossed with “90” on one side and plain on the other, with dimensions of 8,1 x 8,3 mm ± 7,5 %.

ADCO ETORICOXIB 120 mg: Pale green, apple-shaped, biconvex film coated tablet, debossed with “120” on one side and plain on the other, with dimensions of 8,9 x 9,2 mm ± 7,5 %.

ADCO ETORICOXIB 30 mg, 60 mg, 90 mg, or 120 mg film coated tablets are packed in aluminium-aluminium blisters formed of:

- Aluminium forming foil consisting of a 50 µm aluminium layer coated with a 25 µm oPA (oriented polyamide) film coated aluminium layer on one side and 60 µm polyvinyl chloride (PVC) on the other side,
- an aluminium lidding foil consists of a 40 µm aluminium layer coated with a print primer for better printing performance on one side and with a heat-seal lacquer composed of vinyl acrylic resins on the other side.

Pack sizes

ADCO ETORICOXIB 30 mg: 2, 7, 14, 20, 28, 49 tablets or multi-packs containing 98 (2 packs of 49) tablets

ADCO ETORICOXIB 60 mg, 90 mg and 120 mg: 2, 5, 7, 10, 14, 20, 28, 30, 49, 50, 84, 100 tablets or multi-packs containing 98 (2 packs of 49) tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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ADCO ETORICOXIB 60 mg: 50/3.1/0301

ADCO ETORICOXIB 90 mg: 50/3.1/0302

ADCO ETORICOXIB 120 mg: 50/3.1/0303

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