Approved Patient Information Leaflet

ETORICOXIB 30 mg AUSTELL

ETORICOXIB 60 mg AUSTELL

ETORICOXIB 90 mg AUSTELL

ETORICOXIB 120 mg AUSTELL

SCHEDULING STATUS

S3

ETORICOXIB 30 mg AUSTELL film-coated tablets.

ETORICOXIB 60 mg AUSTELL film-coated tablets.

ETORICOXIB 90 mg AUSTELL film-coated tablets.

ETORICOXIB 120 mg AUSTELL film-coated tablets.

Contains sugar (lactose monohydrate).

Each ETORICOXIB 30 mg AUSTELL film-coated tablet contains 2,52 mg lactose monohydrate.

Each ETORICOXIB 60 mg AUSTELL film-coated tablet contains 5,04 mg lactose monohydrate.

Each ETORICOXIB 90 mg AUSTELL film-coated tablet contains 7,56 mg lactose monohydrate.

Each ETORICOXIB 120 mg AUSTELL film-coated tablet contains 10,08 mg lactose monohydrate.

Read all of this leaflet carefully before you start to take ETORICOXIB AUSTELL

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.

ETORICOXIB AUSTELL 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

Austell Pharmaceuticals (Pty) Ltd, 490988-91, Etoricoxib, Film-coated tablets, 30 mg, 60 mg, 90 mg, 120 mg

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

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

What is ETORICOXIB AUSTELL?

- ETORICOXIB AUSTELL contains the active substance etoricoxib. ETORICOXIB AUSTELL is one of a group of medicines called selective COX-2 inhibitors. ETORICOXIB AUSTELL works by blocking the action of an enzyme called COX-2 and in this way reduces inflammation and pain in the body. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

What is ETORICOXIB AUSTELL used for?

- ETORICOXIB AUSTELL helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with
  - osteoarthritis - 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
  - rheumatoid arthritis - a long-term (chronic) 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
  - ankylosing spondylitis - an inflammatory disease of the spine and large joints

  - gout - a disease of sudden, recurring attacks of very painful inflammation and redness in the joints. It is caused by deposits of mineral crystals/uric acid in the joint.
- ETORICOXIB AUSTELL is also used in people 16 years of age and older for the short-term treatment of
  - acute pain for a maximum period of 8 days
  - menstrual pain
  - moderate pain after dental surgery.

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

Do not take ETORICOXIB AUSTELL

- if you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of ETORICOXIB AUSTELL (listed in section 6)
- if you have taken aspirin or any other NSAIDs (nonsteroidal anti-inflammatory drugs) including COX-2 inhibitors such as ETORICOXIB AUSTELL previously, and have experienced asthma (wheezing and being unable to breathe easily), nasal irritation, nasal polyps (soft, painless, noncancerous growths on the lining of your nasal passages or sinuses that hang down like teardrops or grapes) or allergic symptoms such as swelling of the face, lips, tongue or throat and/or itching skin rash
- if you have a current stomach ulcer or bleeding in the stomach or intestines
- if you have a serious liver disease
- if you have serious kidney disease
- if you have hypertension (high blood pressure) which is not well controlled
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding 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 your doctor has diagnosed heart problems including heart failure (moderate or severe types), chest pain (angina) or if you have had a heart attack, bypass surgery, narrow or blocked arteries of the extremities (peripheral vascular disease), or any kind of stroke (including mini-stroke or a transient ischaemic attack- TIA). ETORICOXIB AUSTELL may 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 a stroke (see section 2, Warnings and precautions)
- if you are taking a medicine called lithium (used to treat bi-polar disorder) or digoxin (medicine for heart failure and irregular heart rhythm).

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking ETORICOXIB AUSTELL.

Warnings and precautions

Take special care with ETORICOXIB AUSTELL.

Talk to your doctor before taking or whilst taking ETORICOXIB AUSTELL if you:

- have a history of stomach ulcers or stomach bleeding
- have a history of heart failure, heart attack or any other form of heart disease
- have a history of stroke or mini-stroke
- have conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or if you are a smoker
- have a history of high blood pressure. ETORICOXIB AUSTELL can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time to make sure that it is safe to continue treatment
- have swelling due to fluid retention
- if you have a history of kidney or liver disease

- have serious skin reactions. Most of these skin reactions occur in the first month of treatment and can be fatal (see section 4). At the first appearance of skin rash, peeling of the skin, and/or blisters and sores or any other sign of allergy, you must discontinue ETORICOXIB AUSTELL immediately and see a doctor
- experience a serious allergic syndrome called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can take 3 weeks up to 3 months to appear after you've taken ETORICOXIB AUSTELL. The symptoms of DRESS include a severe rash and a potentially life-threatening swelling of most of the body's skin surface followed by redness and peeling of the skin, facial swelling, enlargement of one or more lymph nodes, the bean-shaped glands found in the neck, armpits, chest, groin, and abdomen and high fever. In blood tests there can be an increase in red blood cells (eosinophils), high counts of atypical white blood cells (lymphocytes – blood cells which are activated to respond to infections) and abnormal results in liver function tests. This adverse drug reaction can also cause damage to other organs in your body like your lungs, pancreas, kidneys, brain and many others and can be life-threatening (see section 4). If you experience any of these symptoms, you must discontinue ETORICOXIB AUSTELL immediately and see a doctor
- are dehydrated, for example by a prolonged bout of vomiting or diarrhoea
- are being treated for an infection. ETORICOXIB AUSTELL can mask or hide a fever, which is a sign of infection
- are a woman trying to become pregnant.

There appears to be a higher risk of cardiovascular events such as heart attack and strokes with higher doses and longer duration of treatment. It is important that you use the lowest dose that controls your pain and you should not take ETORICOXIB AUSTELL for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses. For this reason, your doctor may discuss your treatment with you periodically.

If you suffer from heart problems, kidney or liver disease or are elderly (older than 65 years of age) your doctor will want to perform regular checks on you. This includes checking your blood pressure periodically as ETORICOXIB AUSTELL can increase blood pressure in some people.

Children and adolescents

Safety and efficacy in children have not been established. Do not give this medicine to children and adolescents under 16 years of age.

Other medicines and ETORICOXIB AUSTELL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ETORICOXIB AUSTELL may weaken the effects of the following medicines

- medicines that thin your blood (anticoagulants), such as warfarin
- 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).

ETORICOXIB AUSTELL may strengthen the effects and/or increase your risk of side effects when used in combination with the following medicines

- aspirin, the risk of stomach ulcers is greater if you take ETORICOXIB AUSTELL with aspirin.
    - aspirin for prevention of heart attacks or stroke:

ETORICOXIB AUSTELL 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 AUSTELL.

- ciclosporin or tacrolimus (medicines used for suppressing the immune system) - the combination may have increased side effects on kidneys function
- lithium (a medicine used to treat some types of depression)
- methotrexate (a medicine used for suppressing the immune system, and often used in rheumatoid arthritis)
- birth control pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- 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).

The following medicine may weaken the effects of ETORICOXIB AUSTELL

- rifampicin (an antibiotic used in the treatment of tuberculosis).

ETORICOXIB AUSTELL with food and drink

Take ETORICOXIB AUSTELL tablets with a drink of water. You may take ETORICOXIB AUSTELL with or without food. The onset of the effect of ETORICOXIB AUSTELL may be faster when taken 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 professional for advice before taking this medicine.

Pregnancy

ETORICOXIB AUSTELL must not be taken if you are pregnant. If you are pregnant, or think that you may be pregnant or if you plan on falling pregnant, do not take ETORICOXIB AUSTELL. If while taking ETORICOXIB AUSTELL you become pregnant, stop taking the tablets and consult your doctor.

- Using pain-relieving and fever-reducing nonsteroidal anti-inflammatory drugs (NSAIDs) such as ETORICOXIB AUSTELL around 20 weeks or later in pregnancy may cause kidney problems in your unborn baby, which can lead to low levels of amniotic fluid that surrounds your baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Complications such as the permanent tightening of the muscles, tendons, skin, and nearby tissues in limbs that causes the joints to shorten and become very stiff or the delay in the foetus' lung maturation can occur with low levels of the amniotic fluid.
- The use of ETORICOXIB AUSTELL during the third trimester (i.e. from 30 weeks and later) of pregnancy is contraindicated. In the third trimester ETORICOXIB AUSTELL may result in the premature closure of the foetal ductus arteriosus (i.e. the too early constriction of the normal foetal artery connecting the main body artery (aorta) and the main lung artery (pulmonary artery) allowing the foetus' blood to detour away from the lungs before birth). This can cause persistent pulmonary hypertension (high blood pressure) of the unborn baby and lead to progressive right heart dysfunction, heart failure, a serious condition defined as abnormal accumulation of fluid in two or more foetal compartments (called foetal hydrops) and death before birth of the baby.

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Breastfeeding

If you are breastfeeding or planning to breastfeed your baby, consult your doctor before taking ETORICOXIB AUSTELL. Do not breastfeed your baby if you are using ETORICOXIB AUSTELL**.**

Fertility

ETORICOXIB AUSTELL is not recommended in women attempting to become pregnant.

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking etoricoxib as in ETORICOXIB AUSTELL.

ETORICOXIB AUSTELL. Do not drive or operate machinery if you experience dizziness or sleepiness and until you know how ETORICOXIB AUSTELL affects you.

ETORICOXIB AUSTELL contains lactose

ETORICOXIB AUSTELL contains lactose which is a sugar. If you have been told by your doctor that you are unable to tolerate some sugars, contact your doctor before taking ETORICOXIB AUSTELL.

3. How to take ETORICOXIB AUSTELL

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

Always take ETORICOXIB AUSTELL exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

How much to take

Your doctor will decide on the dose of ETORICOXIB AUSTELL you should use and for how long you should use it.

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 ETORICOXIB AUSTELL 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 recommended doses are as follows:

- ***Osteoarthritis***

  30 mg once daily increase to a maximum of 60 mg once a day if needed.
- ***Rheumatoid arthritis***

  60 mg once a day, increased to a maximum of 90 mg once daily if needed.
- ***Ankylosing spondylitis***

  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*

    120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.
  - *Menstrual pain*

    120 mg once daily, which should only be used for the acute painful period before and during menstruation
  - *Postoperative dental surgery pain*

90 mg once daily, which should only be used for the acute painful period.

If you have liver problems

- If you suffer from liver disease you doctor may decrease the dose or tell you to take a dose every other day.
- 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 or 60 mg every other day.
- You should not use ETORICOXIB AUSTELL if you have severe liver disease.

How to take it

ETORICOXIB AUSTELL can be taken with or without food (see section 2, ETORICOXIB AUSTELL with food and drink).

Swallow the tablets whole with a drink of water. Do not chew them.

If you have the impression that ETORICOXIB AUSTELL is too strong or too weak, tell your doctor or pharmacist.

If you take more ETORICOXIB AUSTELL 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 your dose of ETORICOXIB AUSTELL

It is important to take ETORICOXIB AUSTELL as your doctor has prescribed. If you miss a dose, just resume your schedule of taking ETORICOXIB AUSTELL the next day. Do not take double doses to make up for a forgotten individual dose.

4. Possible side effects

ETORICOXIB AUSTELL can have side effects.

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

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

- wheezing or having difficulty breathing with or without swelling of the throat and face as these may be signs of an allergic reaction
- fever (high temperature) and sore throat with a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions. Your eyes may also be affected and may be red and swollen. These may be signs of a severe skin reaction
- if you have difficulty urinating or notice that your urine has changed colour or if you have severe pain in the flank (area between your ribs and hips). These may be signs of effects on how your kidneys work, especially if you have kidney problems or heart failure
- dark urine, yellowing of your skin or the whites of your eyes. These may be signs of a problem with your liver
- noticing a sudden numbness or weakness of the face arm or leg especially on one side of the body, sudden confusion, having trouble talking or understanding, difficulty seeing in one or

both eyes, sudden trouble walking, dizziness, lack of balance or coordination. These may be signs of a stroke or transient ischaemic attack (TIA)

- serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) which can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first months of treatment (see section 2. Warnings and precautions)
- a serious allergic syndrome called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can involve severe rash, redness and peeling of the skin, facial swelling, enlargement of one or more lymph nodes, high fever and damage to several organs such as your lungs, pancreas, kidneys, brain and many others. This severe allergic reaction can be life-threatening and can take 3 weeks up to 3 months to appear after you've taken ETORICOXIB AUSTELL (see section 2. Warnings and precautions).

These are very serious side effects. If you have them, 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:

- a build-up of fluid in the body, often seen as swelling in the legs and feet (oedema/fluid retention)
- your blood pressure reading is higher than normal
- blurred vision together with chest pain, confusion, having a seizure ("fit"). These may be symptoms of hypertensive crisis

- you are suffering from infections more often such as gastroenteritis ("stomach flu" or infectious diarrhoea), upper respiratory infection (colds), urinary tract infections
- hallucinations (seeing or hearing things that are not there)
- having the sensation of being able to feel your heartbeat (palpitations)
- severe pain in the stomach with or without vomiting of fresh blood or coffee ground material or tarry stools. These may be symptoms of a gastroduodenal ulcer with perforation and bleeding
- decrease in blood sodium (you may feel dizzy, weak, confused, sleepy or very tired)
- swelling of your limbs, especially your feet or feeling short of breath or breathlessness even while resting or a persistent wheezing together with fatigue (extreme tiredness). These may be signs of your heart failing.
- tachycardia (feeling your heart beat fast), dysrhythmia (you're your heart is not beating rhythmically), severe increase in blood pressure
- thrombocytopenia (this is a decrease in the cells which help your blood to clot). You may notice that it takes longer for your blood to clot after an injury
- blurred vision.

Tell your doctor if you notice any of the following:

Frequent:

- dry socket (inflammation and pain after a tooth extraction)
- dizziness, headache
- gastrointestinal disorders such as pain in the abdomen, flatulence (passing wind), heartburn, diarrhoea, dyspepsia (feeling of indigestion), epigastric discomfort, nausea
- ecchymosis (bruising of the skin)
- feeling extremely tired
- changes in blood tests related to your liver.

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Less frequent:

- increase or decrease in appetite, weight gain
- feeling anxious, depression (feeling in sad mood for long periods of time), feeling confused
- insomnia (being unable to fall asleep or stay asleep), paraesthesia (a tingling sensation in the skin "pins and needles") or hypaesthesia (being unable to feel sensation in the skin)
- conjunctivitis ("red eye")
- tinnitus (a ringing sound in the ear), vertigo (feeling dizzy)
- cough, epistaxis (bleeding from the nose)
- abdominal distention (bloating and swelling of the stomach), acid reflux, bowel movement pattern change, constipation, dry mouth, oesophagitis (inflammation of the "food pipe"), oral ulcer, vomiting (being sick), inflammation of the pancreas
- pruritus (itching of the skin), rash, erythema (redness of the skin), urticaria ("hives")
- cramps or spasms in the muscles, "stiffness" of muscles
- chest pain
- on testing of your blood the following may be noticed: blood urea increased, creatinine phosphokinase increased, haematocrit decreased, haemoglobin decreased, hyperkalaemia, serum creatinine increased, uric acid increased, decreased number of red blood cells, decreased number of white blood cells.

Frequency unknown:

- feeling restless
- dysgeusia (taste disturbances)
- somnolence (feeling sleepy).

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 or pharmacist. 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 ETORICOXIB AUSTELL.

5. How to store ETORICOXIB AUSTELL

- Store in the original packaging. Keep blister packs in the carton until required for use.
- Store at or below 25 °C. Protect from light.
- Do not use ETORICOXIB AUSTELL after the expiry date printed on the label, container or blister.
- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ETORICOXIB AUSTELL contains

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

- The other ingredients are:

Tablet core

calcium hydrogen phosphate anhydrous

croscarmellose sodium

hydroxypropyl cellulose

lactose monohydrate

magnesium stearate

microcrystalline cellulose.

Tablet coating

30 mg tablets contain Opadry II Green 32K510009 (consisting of hypromellose, lactose monohydrate, titanium dioxide, triacetin, FD & C blue #2 (indigo carmine aluminium lake), iron oxide yellow).

60 mg tablets contain Opadry II Green 32K510012 (consisting of hypromellose, lactose monohydrate, titanium dioxide, triacetin, FD & C blue #2 (indigo carmine aluminium lake), iron oxide yellow).

90 mg tablets contain Opadry II White 32K580000 (consisting of hypromellose, lactose monohydrate, titanium dioxide, triacetin).

120 mg tablets contain Opadry II Green 32K510013 (consisting of hypromellose, lactose monohydrate, titanium dioxide, triacetin, FD & C blue #2 (indigo carmine aluminium lake), iron oxide yellow).

What ETORICOXIB AUSTELL looks like and contents of the pack

ETORICOXIB AUSTELL tablets are available in four strengths:

ETORICOXIB 30 mg AUSTELL: Blue-green, apple-shaped, biconvex film coated tablets engraved ‘30’ on one face with the other face plain.

ETORICOXIB 60 mg AUSTELL: Dark-green, apple-shaped, biconvex film coated tablets engraved ‘60’ on one face with the other face plain.

ETORICOXIB 90 mg AUSTELL: White, apple-shaped, biconvex film coated tablets engraved ‘90’ on one face with the other face plain.

ETORICOXIB 120 mg AUSTELL: Pale-green, apple-shaped, biconvex film-coated tablets engraved ‘120’ on one face with the other face plain.

ETORICOXIB 30, 60, 90 and 120 mg AUSTELL are packed in silver aluminium/aluminium blister strips, in pack sizes of 10 (1 x 10), 30 (3 x 10), 60 (6 x 10), 7 (1 x 7), 14 (2 x 7) or 28 (7 x 4) tablets.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Registration numbers

ETORICOXIB 30 mg AUSTELL: 49/3.1/0988

ETORICOXIB 60 mg AUSTELL: 49/3.1/0989

ETORICOXIB 90 mg AUSTELL: 49/3.1/0990

ETORICOXIB 120 mg AUSTELL: 49/3.1/0991

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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