SCHEDULING STATUS S3

THRYTIX 60 Tablet

THRYTIX 90 Tablet

THRYTIX 120 Tablet

Etoricoxib

THRYTIX 60: Contains sugar (lactose monohydrate) 1,68 mg per tablet.

THRYTIX 90: Contains sugar (lactose monohydrate) 2,52 mg per tablet.

THRYTIX 120: Contains sugar (lactose monohydrate) 3,36 mg per tablet.

Read all of this leaflet carefully before you start taking THRYTIX

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

1. **What THRYTIX is and what it is used for**

THRYTIX helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with rheumatoid arthritis, ankylosing spondylitis and gout.

THRYTIX is also used for the short term treatment of moderate pain, pain after dental surgery in people 16 years of age and older for a maximum of 8 days.

THRYTIX is used for the treatment of painful period.

2. What you need to know before you take THRYTIX

Do not take THRYTIX:

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of THRYTIX
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors
- if you develop signs of asthma, a runny or blocked nose, growths in the nasal passage or itching and swelling of the skin (e.g., face, eyelids, mouth or tongue) after taking aspirin or other non-steroidal anti-inflammatory medicines(NSAIDs) including THRYTIX
- if you have a current stomach ulcer or bleeding in your stomach or intestines
- if you have serious liver disease
- if you have serious kidney disease
- if you are or could be pregnant or are breast-feeding (see ‘Pregnancy and Breastfeeding’)
- if you are under 16 years of age
- if you have inflammatory bowel disease, such as Crohn’s Disease, Ulcerative Colitis, or Colitis
- 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 your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain)
- if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)

- if you have had 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 are having bypass surgery.

Warnings and precautions

Take special care with THRYTIX :

- THRYTIX should be taken for the shortest duration possible and the lowest effective daily dose should be used
- if you are taking low-dose aspirin with THRYTIX as the rate of stomach ulcers or other stomach and intestine complications can increase
- THRYTIX is not a substitute for aspirin for cardiovascular prophylaxis because of its lack of effect on platelets
- if a serious skin reaction is noticed in patients with a history of any allergy

- if you have a history of stomach bleeding or ulcers
- if you are dehydrated, for example by a prolonged bout of vomiting or diarrhoea
- if you have swelling due to fluid retention
- if you have a history of heart failure, or any other form of heart disease
- if you have a history of high blood pressure. THRYTIX 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. THRYTIX can mask or hide a fever, which is a sign of infection
- if you have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease
- if you are a woman trying to become pregnant
- if you are over 65 years of age. Your doctor will want to appropriately keep a check on you if you are elderly and have kidney, liver or heart problems.
- If you develop a skin rash, fever, swelling of lymph nodes and and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Other medicines and THRYTIX

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

Tell your doctor if you are taking any of the medicines listed below, as special care should then be taken:

- 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) as taking lithium together with THRYTIX may lead to toxic blood concentration of lithium
- 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)
- 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 THRYTIX with aspirin.
    - aspirin for prevention of heart attacks or stroke:

      THRYTIX 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 THRYTIX.

THRYTIX with food and drink

THRYTIX can be taken with or without food.

Pregnancy, breast-feeding and fertility

Do not take THRYTIX if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby while taking THRYTIX, please consult your doctor, pharmacist or other health care professional for advice before taking THRYTIX.

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking THRYTIX.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

THRYTIX contains lactose monohydrate:

THRYTIX tablets contain lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take THRYTIX.

3. How to take THRYTIX

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

Always take THRYTIX exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

If you are elderly and have kidney, liver or heart problems, your doctor will want to appropriately keep a check on you. If you show deterioration during treatment with THRYTIX, your doctor will take appropriate measures, including stopping THRYTIX treatment.

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 THRYTIX 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 usual dose is:

Rheumatoid arthritis

The recommended dose is 90 mg once a day.

Ankylosing spondylitis

The recommended dose is 90 mg once a day.

Acute pain conditions

The recommended dose is 90 or 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

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.

Primary dysmenorrhea

The recommended dose is 120 mg once a day.

Postoperative dental surgery pain

The recommended dose is 90 mg once day.

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.

Use in children and adolescents

THRYTIX should not be taken by 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

- THRYTIX is for oral use. Take the tablets once a day. THRYTIX can be taken with or without food.

If you have the impression that the effect of THRYTIX is too strong or too weak, tell your doctor or pharmacist.

If you take more THRYTIX 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 THRYTIX

It is important to take THRYTIX as your doctor has prescribed. If you miss a dose, just resume your usual schedule the following day. Do not take a double dose to make up for the forgotten tablet.

4. Possible side effects

THRYTIX can have side effects.

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

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

- 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, liver failure,
- severe or continual stomach pain or your stools become black,
- a severe allergic reaction or hypersensitivity 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/anaphylactic/anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention).
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

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

- palpitations (fast or irregular heartbeat), irregular heart rhythm (dysrhythmia),
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack,
- chest pain,
- flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure, inflammation of the blood vessels,
- wheezing or shortness of breath (bronchospasms).

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:

- stomach pain
- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- dizziness, headache
- increased blood pressure
- 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
- weakness and fatigue, flu-like illness
- changes in blood tests related to your liver

Less frequent or frequency unknown side effects

- bruising
- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach), upper respiratory infection, urinary tract infection
- changes in laboratory values (decreased number of red blood cells, decreased number of white blood cells, platelets decreased)
- 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)
- 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
- confusion, restlessness
- liver problems (hepatitis)
- low blood levels of sodium

In clinical studies, a higher incidence of adverse experiences was seen in older patients compared to younger patients.

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 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 THRYTIX.

5. How to store THRYTIX

Store all medicines out of reach of children.

Store at or below 30 ºC. Protect from Moisture.

Store in the original package.

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

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 THRYTIX contains

The active ingredient is etoricoxib.

The other ingredients are Calcium phosphate dibasic anhydrous, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate

and microcrystalline cellulose.

Coating:

- **THRYTIX 60:** Opadry II 32K510024 green – FD & C Blue #2/Indigo carmine aluminium lake, HPMC 2910/Hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin.
- **THRYTIX 90:** Opadry II 32K580000 white – HPMC 2910/Hypromellose, lactose monohydrate, titanium dioxide, triacetin.
- **THRYTIX 120:** Opadry II 32K510022 green – FD & C Blue #2/Indigo carmine aluminium lake, HPMC 2910/Hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, triacetin.

What THRYTIX looks like and contents of the pack

THRYTIX 60: Green, round, biconvex, film-coated tablets debossed with '444' on one side and 'L' on other side.

THRYTIX 90: White to off-white, round, biconvex, film-coated tablets debossed with '445' on one side and 'L' on other side.

THRYTIX 120: Pale - green, round, biconvex, film-coated tablets debossed with '446' on one side and 'L' on other side.

Contents of the pack:

Tablets are packed in cold form blisters. Each blister strip contains 8 tablets. There are 8 tablets in a cardboard box.

Tablets are packed in a PVC-PVDC or PVC/PE/PVDC blister pack. Each blister pack contains 10 tablets. There are 10 or 30 tablets in a cardboard box.

Holder of Certificate of Registration

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