SCHEDULING STATUS

S3

ETOFLAM 60

ETOFLAM 90

ETOFLAM 120

Etoricoxib

Contains sugar: Lactose

Read all of this leaflet carefully before you start taking ETOFLAM.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- **ETOFLAM** 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 **ETOFLAM** is and what it is used for

2. What you need to know before you take **ETOFLAM**

3. How to take **ETOFLAM**

4. Possible side effects

5 How to store **ETOFLAM**

6. Contents of the pack and other information

1. What ETOFLAM is and what is it used for:

ETOFLAM is a member of a group of medicines called non-steroidal anti-inflammatory drugs

(NSAIDS) that are used to reduce pain and inflammation. **ETOFLAM** is a selective COX-2 inhibitor.

Your doctor has prescribed **ETOFLAM** for one of the following conditions:

- 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 ETOFLAM:

Do not take ETOFLAM:

- If you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of **ETOFLAM**.
- If you have an active stomach ulcer or bleeding in the stomach or intestines
- If you have serious liver disease
- If you have serious kidney disease
- If you have previously experienced any of the following after taking aspirin (acetylsalicylic acid) or other non-steroidal anti-inflammatory drugs, including COX-2 inhibitors: asthma (wheezing or inability to breathe easily), nasal irritation, nasal polyps or allergic symptoms such as swelling of the face, lips, tongue, throat and/or itching skin rash.

- If you have high blood pressure which has not been adequately controlled by treatment
- If you are pregnant or breastfeeding
- 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). Chest pain (angina) or if you have had a heart attack, bypass surgery, narrow or blocked arteries of the extremities (peripheral arterial disease), or any kind of stroke (including mini-stroke, transient ischaemic attack or TIA).
- **ETOFLAM** 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 stroke.
- If you are taking Lithium (a medicine used to treat a certain type of depression)
- If you are taking digoxin (medicine that helps make the heart beat stronger)

Warnings and precautions

Take special care with ETOFLAM:

- If you have a history of kidney disease
- If you have a history of liver disease
- If you have a history of heart failure, heart attack, or any other form of heart disease
- Narrow or blocked arteries of the extremities
- If you have dehydration (for example dehydration caused by a prolonged bout of vomiting or diarrhoea)
- If you have a history of high blood pressure
- If you have swelling due to fluid retention
- If you have a history of stroke or mini-stroke

- If you have a history of stomach bleeding or ulcers
- If you have conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking.
- If you are elderly (i.e. over 65 years of age), or have kidney, liver or heart disease, your doctor will want to keep a regular check on you
- If you develop any symptoms that could indicate a severe allergic reaction such as inability to breathe or a serious skin reaction, you must consult a doctor urgently.
- If you are taking warfarin or any other medicines that prevents blood clotting.
- If you are taking aspirin (acetylsalicylic acid), (even at low dose for heart protective purposes) or other NSAID's (non-steroidal anti-inflammatory drugs) like ibuprofen.

There appears to be a higher risk of cardiovascular events with higher doses and longer duration of treatment.

Serious skin reactions (e.g. Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) which may be fatal, may occur.

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 **ETOFLAM** for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

ETOFLAM 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.

Children and adolescents:

Safety and efficacy in children have not been established. Therefore, **ETOFLAM** should not be given to children.

Other medicines and ETOFLAM:

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

- Warfarin (a blood thinner)
- Rifampicin (an antibiotic)
- Diuretics (water tablets)
- ACE inhibitors and angiotensin receptor blockers e.g digoxin (medicines used for high blood pressure and heart failure)
- Lithium (a medicine used to treat a certain type of depression)
- Birth control pills
- Methotrexate (a medicine used for suppressing the immune system).
- Ciclosporin and tacrolimus medicines used for suppressing the immune system)
- Furosemide (water tablets)
- Hormone replacement therapy
- Aspirin. **ETOFLAM** can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because **ETOFLAM** cannot substitute aspirin for this purpose. Salbutamol used to prevent and treat wheezing and shortness of breath caused by breathing problems (e.g., asthma)
- Minoxidil used to help with hair growth

ETOFLAM with food, drink, and alcohol:

ETOFLAM may be taken with or without food.

Pregnancy and 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.

ETOFLAM tablets should not be taken during pregnancy.

If you are using **ETOFLAM** you should not breastfeed your baby.

Driving and using machines:

Should you feel lightheaded or dizzy after taking **ETOFLAM**, please refrain from driving or operating machinery.

It is not always possible to predict to what extent **ETOFLAM** 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 **ETOFLAM** affects them.

ETOFLAM contains:

ETOFLAM contains sugar (lactose). If you have been told by your doctor that you have intolerance to some sugars, you should contact your doctor before taking **ETOFLAM.**

3. HOW TO TAKE ETOFLAM

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

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

The usual dose is:

ETOFLAM should be taken once a day.

ETOFLAM can be taken with or without food.

For relief of symptoms of rheumatoid arthritis:

- The recommended dose is 90 mg once a day. In some patients, 60 mg once daily may provide adequate therapeutic effect.

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:

- 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 the relief of pain after dental surgery

- The recommended dose is 90 mg once daily.

Your doctor will tell you how long your treatment with **ETOFLAM** will last. Do not stop treatment early if you have the impression that the effect of **ETOFLAM** is too strong or too weak, tell your doctor or pharmacist.

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 60 mg **every other day**

IF YOU TAKE MORE ETOFLAM 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 ETOFLAM:

Try to take **ETOFLAM** as prescribed by your healthcare professional. However, if you miss a dose, do not take a double dose to make up for the forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

ETOFLAM can have side-effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- an allergic reaction such as a rash, hives, itching or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing
- shortness of breath, severe chest pains, severe headaches with increasing confusion or blurred vision with ankle swelling. These may be signs you have dangerously high blood pressure
- yellowing of the skin and eyes, dark urine, tiredness, fever, feeling sick (nausea), weakness, drowsiness and stomach pain. These may be signs of serious liver problems
- severe or continual stomach pain, black tar-like stools or bloodstained stools, being sick (vomiting) which may contain blood, bloated stomach, loss of appetite or feeling sick (nausea). These may be signs of serious problems with your stomach, intestine or pancreas
- a serious skin condition with severe blisters and bleeding in the lips, eyes, mouth and nose (Stevens-Johnson syndrome), or severe skin reactions which start as painful

red areas then large blisters and ends with peeling of layers of skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis). A sudden swelling in your lymph nodes and face, a fever and rash. (Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS)

- an increase in the number of infections which you may see as fevers, severe chills, sore throat or mouth ulcers. These may indicate you have a low number of white blood cells
- an abnormally or dangerously fast heart beat
- sudden collapse, numbness or weakness in the arms or legs, headache, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred, mixed up or loss of speech. These may be signs of a stroke or mini stroke caused by a clot or bleed affecting blood supply to part of the brain
- heavy or pressing sensation on your chest with chest pain and shortness of breath on exercise (these may be signs you have angina)
- sudden chest pain which may spread to the neck or arm, with a shortness of breath and clammy feeling. These may be signs of a heart attack or other problems with your heart
- a reduction in the working of the heart, which may cause tiredness, weakness and/or fluid retention such as swelling of the legs and ankles, difficulty breathing including coughing up frothy or watery phlegm
- producing little or no urine, cloudy urine or blood in the urine, pain when passing urine or lower back pain. These may be signs of serious problems with your kidney.

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

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

- stomach pain
- dry socket (inflammation and pain after tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- dizziness, headache
- fast or irregular heartbeat (palpitations), irregular heart rhythm (dysrhythmia),
- increased blood pressure (hypertension)
- constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhoea, indigestion (dyspepsia)/stomach discomfort, feeling sick (nausea), being sick (vomiting), inflammation of the food pipe
- changes in blood tests related to your liver
- bruising
- weakness and tiredness, flu-like illness

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

Tell your doctor if you notice any of the following:

Less Frequent:

- chest or throat infection
- discomfort or a burning pain when passing water. This may be a sign you have a urinary tract infection
- tiredness, shortness of breath, coldness in your hands and feet and pale skin. These may be signs of a low number of red blood cells

- unexplained bruising or bleeding more frequently or for longer than normal. These may be signs of a low number of platelets
- appetite increases or decreases, weight gain
- anxiety, depression, decreases in mental sharpness; seeing, feeling or hearing things that are not there (hallucinations)
- changes in taste, inability to sleep, numbness or tingling of the hands or feet, reduced skin sensitivity, sleepiness
- blurred vision, eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- changes in the electrical activity of the heart
- flushing, inflammation of the blood vessels
- cough, nose bleed
- changes in your bowel habits, dry mouth, irritable bowel syndrome
- muscle cramp or spasm, muscle pain or stiffness
- high levels of potassium in your blood, changes in blood or urine tests relating to your kidneys
- confusion, restlessness
- low blood levels of sodium.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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 **ETOFLAM**.

5. How to store ETOFLAM

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

Do not use this medicine after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

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

Store **ETOFLAM** at or below 30 °C in an outer carton. Protect from moisture.

6. Contents of the pack and other information

What ETOFLAM contains:

The active substance is: Etoricoxib

The other ingredients are:

Calcium phosphate dibasic anhydrous, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, hydroxy propyl cellulose, hypromellose, lactose monohydrate, titanium dioxide, triacetin, Fd&C blue 2 /indigo carmine aluminium lake colourant.

What ETOFLAM looks like and contents of the pack

ETOFLAM 60: A green, round, biconvex, film-coated tablet debossed with ‘444’ on one side and ‘**L**’ on the other side.

ETOFLAM 90: A white to off-white, round, biconvex, film-coated tablet debossed with ‘445’ on one side and ‘**L**’ on the other side.

ETOFLAM 120: A pale-green, round, biconvex, film-coated tablet debossed with ‘446’ on one side and ‘**L**’ on the other side.

ETOFLAM 60 mg tablets are available in aluminium foil and CFB foil or aluminium foil and PVC/PVDC foil or aluminium foil and PVC/PE/PVDC foil blister packs of 8's and 30's in an outer carton.

ETOFLAM 90 mg and 120 mg tablets are available in aluminium foil and CFB foil or aluminium foil and PVC/PVDC foil or aluminium foil and PVC/PE/PVDC foil blister packs of 8's and 30's in an outer carton.

Holder of Certificate of Registration

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ETOFLAM 60: A 50/3.1/0053.050

ETOFLAM 90: A 50/3.1/0054.051

ETOFLAM 120: A 50/3.1/0055.052

Access to the corresponding Professional information is contained in the packaging of ETOFLAM.

Follow the link for the corresponding Professional Information for CONTREZ: pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below:

