PATIENT INFORMATION LEAFLET FOR

ETIFLAM 60/ 90/ 120

SCHEDULING STATUS: **S3**

ETIFLAM 60 (60 mg film-coated tablets)

ETIFLAM 90 (90 mg film-coated tablets)

ETIFLAM 120 (120 mg film-coated tablets)

Etoricoxib

Contains sugar.

ETIFLAM 60: Lactose monohydrate (2,8 mg)

ETIFLAM 90: Lactose monohydrate (4,2 mg)

ETIFLAM 60: Lactose monohydrate (5,6 mg)

Read all of this leaflet carefully before you start taking ETIFLAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- ETIFLAM 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 ETIFLAM is and what it is used for

ETIFLAM belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Medicines belonging to this class are used in the treatment of pain, fever, and inflammation.

ETIFLAM film-coated tablets are used in the treatment of:

- Rheumatoid arthritis (joint diseases)
- Ankylosing spondylitis (spinal joint disease)
- Acute gouty arthritis, limited to a maximum of 8 days.
- Short-term relief of acute pain, treatment limited to a maximum period of 8 days.
- Primary dysmenorrhea (painful menstruation)
- Moderate to severe acute post-operative pain associated with dental surgery

2. What you need to know before you take ETORICOXIB

Do not take ETIFLAM if you:

- are allergic to etoricoxib or any other ingredients of ETIFLAM
- have stomach / gut ulcers or any other complications of the gut such as stomach / intestinal bleeding, signs include tarry or black stools, vomiting blood, diarrhoea and/or abdominal (stomach) pain.
- have severe liver or kidney disease.

- have previously experienced allergic reactions (signs include facial swelling, rash, asthma, or flu-like symptoms such as postnasal drip, persistent stuffiness, facial pain, headache, or runny nose) to NSAIDs such as aspirin.
- are pregnant or breastfeeding.
- are younger than 16 years of age (parents, guardians or other care givers must not give ETIFLAM to children under 16 years of age)
- have uncontrolled high blood pressure.
- have inflammatory bowel syndrome (a condition characterised by food intolerance, alternating constipation and diarrhoea, abdominal cramping and constant gas and bloating)
- suffered from heart attack, stroke, or any other heart problems.
- are having heart bypass surgery.

Warnings and precautions

Take special care with ETIFLAM if you have

Allergic reactions

Serious skin reaction which can be fatal can occur. If you have a history of allergies, you might be at risk of serious skin reactions. Discontinue treatment if you suspect any development of skin reactions such as rashes, itchiness, or any other form of allergies. Other forms of allergies can be indicated by mouth ulcers, sneezing, swelling of the mouth, throat, tongue, or eyes and breathing or swallowing difficulties.

Heart problems

Tell your doctor if you are a smoker or are suffering from high blood pressure, diabetes or have been told you have too much fat in your blood as you may be at a high risk of developing heart

disease whilst on ETIFLAM therapy. If you already have high blood pressure, ETIFLAM can worsen your condition. Discontinue treatment and tell your doctor immediately if you suspect that your health has worsened.

If you have a history of heart attacks or strokes, ETIFLAM and other NSAIDs can aggravate your heart condition or cause new heart problems for you. Please ensure that your doctor is made aware of your heart condition before you start treatment with ETIFLAM.

Long treatment periods at high doses can make you more prone to heart problems. You should not take ETIFLAM for periods longer than those prescribed by your doctor.

Gut complications

ETIFLAM can cause upper gastrointestinal (mouth, oesophagus / swallowing tube and stomach sections of your gut) complications such as perforations, ulcers, or bleeding (PUBs), some of which may be fatal. You are at high risk of experiencing these side effects if you are using other NSAIDs such as aspirin concurrently with ETIFLAM, or if you are suffering from pre-existing stomach problems (indicated by ulcers, diarrhoea or tarry / black stools and abdominal pain). Tell your doctor if you are taking other NSAIDs like aspirin or know or suspect that you have stomach complications.

Others

Tell your doctor if you have kidney or liver ailments as ETIFLAM can exacerbate your kidney or liver condition. If you are elderly (above 65 years of age), your ETIFLAM treatment can put you at risk of kidney or liver failure.

Let your doctor know if you have dehydration (loss of body water indicated by fatigue, dizziness, and increased thirst due to exercise, high temperatures or some illnesses) as you need to have acceptable levels of water in your body before treatment with ETIFLAM can commence.

Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

Other medicines and ETIFLAM

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

Aspirin (and other NSAIDs)

Avoid concomitant use of aspirin or other NSAIDs with ETIFLAM due to the increased risk of gastrointestinal (gut) complications that are likely to occur. These events may include ulcers, bleeding (indicated by tarry / black stools), diarrhoea, vomiting blood or dark coffee bean-like substances and stomach pain or abdominal cramps. You must tell your doctor if you are already taking aspirin or other NSAIDs prior to initiating treatment with ETIFLAM. Your doctor will need to take appropriate measures.

Other medicines that increase the risk of gastrointestinal (gut) complications when used together with NSAIDs like ETIFLAM include corticosteroids, selective serotonin reuptake inhibitors (SSRIs), venlafaxine, anti-platelets (clopidogrel and ticlopidine), iloprost, erlotinib, sibutramine, alcohol, bisphosphonates or pentoxifylline. Inform your doctor if you are taking any of these medicines.

Tell your doctor if you are taking any of the following medicines:

- Ciclosporin and tacrolimus: you might develop kidney impairment.
- Warfarin: your blood clotting ability can be negatively affected, this will in turn make you prone to bleeds.
- Rifampicin: the effect of ETIFLAM can be decreased and you might feel that this treatment is not working optimally for you.
- Methotrexate: concomitant use with ETIFLAM can increase the toxicity (poisoning) of methotrexate; you might suffer from adverse effects including abdominal pain, abnormal skin pigmentation, fatigue, nausea, and susceptibility to infections.
- Diuretics, angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) (groups of medicines used in the treatment of high blood pressure): NSAIDs such as ETIFLAM can reduce the effect of high blood pressure medicines, and as a result your kidney or high blood pressure condition can deteriorate. You are at a high risk of kidney failure if you previously suffered from kidney malfunction.
- Lithium: ETIFLAM make you prone to lithium toxicity (poisoning) and you may experience adverse events such as confusion, decreased memory, constipation, diarrhoea, and dry mouth.
- Oral contraceptives: if you are a woman using oral contraceptives such as ethinyl oestradiol you might be at risk of suffering from possibly life-threating blood clots.
- Furosemide: ETIFLAM decreases the blood pressure lowering effect of furosemide.
- Hormone replacement therapy (HRT): if you are a woman taking HRT whilst on ETIFLAM, you might experience oestrogen-related side effects such as breast tenderness or swelling and headaches.

- Antivirals: haematoxicity (or harm to your blood) can occur due to concurrent use of ETIFLAM with zidovudine; this might make you sickly, weak or deteriorate your general health. Concomitant use with ritonavir can increase the incidence of ETIFLAM adverse events.
- Effects on medicines metabolised by sulfotransferases: ETIFLAM causes negative interactions with medicines like oral salbutamol and minoxidil by decreasing their therapeutic effect and in turn, increasing their side effects.
- Digoxin: use of ETIFLAM with digoxin (a medicine used in heart failure) may result in increased concentrations of digoxin, which could lead to toxicity and other adverse events.

ETIFLAM with food, and drink and alcohol

ETIFLAM may be taken with or without food.

Avoid concurrent use of alcohol with ETIFLAM due to increased risk of stomach complications associated with this treatment.

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.

- Do not take ETIFLAM while you are pregnant or breastfeeding.
- You should not take ETIFLAM if you are a fertile woman planning pregnancy

Driving and using machines

Side effects associated with ETIFLAM include dizziness, asthenia and blurred vision may occur. These side effects can alter and negatively affect your ability to drive or operate machines.

ETIFLAM contains Lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ETIFLAM.

3. How to take ETIFLAM

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

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

The usual dose is:

- Rheumatoid arthritis (RA): 90 mg once per day
- Ankylosing spondylitis (AS): 90 mg once per day
- Short-term relief of acute pain: 90 or 120 mg once per day for a maximum of 8 days treatment period
- Acute gouty arthritis: 120 mg once per day for a maximum of 8 days treatment period.
- Dysmenorrhoea (painful menstruation): 120 mg once per day
- Post-operative dental pain: 90 mg once per day.

DO NOT EXCEED THE RECOMMENDED DOSES.

Your doctor will tell you how long your treatment will last.

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

If you take more ETIFLAM 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 ETIFLAM

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

4. Possible Side Effects

ETIFLAM can have side effects

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

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

Less frequent side effects:

- Allergic reaction - swollen face, hives, skin itchiness and/or skin rash
- Stroke
- Heart attack

Side effects with unknown frequencies:

- Anaphylactic shock (allergic reaction indicated by swollen mouth / throat accompanied by difficulty in breathing or swallowing, collapsing and unconsciousness)
- Steven-Johnson syndrome / toxic epidermal necrolysis (life-threatening skin diseases indicated by painful red blisters followed by skin peeling, flu-like symptoms may also develop)
- Jaundice (yellowing of the skin and eyes)
- Liver disease / failure (symptoms may include lower abdominal pain accompanied by vomiting and nausea and disorientation)
- Kidney disease / failure or injury (you may experience severe back pain).

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

Frequent side effects:

- High blood pressure (may be indicated by nosebleeds and shortness of breath)

- Alveolar osteitis (dull, aches or throbbing pain around the tooth area or socket), pain may extent to other parts of the head area.

Less frequent side effects:

- Upper respiratory tract infection, symptoms may include mouth or stomach ulcers and heartburn.
- Gastroenteritis (you may suffer from vomiting and diarrhoea)
- Urinary tract infection, symptoms may include a burning sensation when passing urine, cloudy urine, and lower back / abdominal pain.
- Aseptic meningitis (may be indicated by a stiff neck, headache and being nauseous)
- Chest pain
- Congestive cardiac failure (shortness of breath with exertion, fatigue, feeling faint)
- Pink eye with swollen eyelids
- Palpitations (rapid and irregular heartbeats)
- Coughing
- Breathlessness.

Side effects with unknown frequencies:

- Irregular and abnormal heart rates
- Wheezing, tightness of the chest and dry cough.

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

Tell your doctor if you notice any of the following.

Frequent side effects:

- Nausea
- Bloatedness
- Heartburn
- Flatulence (gas)
- Skin discolouration
- Dizziness
- Headache
- Fatigue
- Flu-like illness.

Less frequent side effects:

- Oral ulcers
- Constipation
- Dry mouth
- Vomiting
- Abnormal intestinal movements
- Nosebleeds
- Swollen limbs (fluid retention)
- Decreased or increased appetite
- Weight gain
- Flushing
- Decreased vision.
- Muscular cramps or spasms

- Bone pain
- Stiffness
- Anxiety
- Depression
- Pins and needles feeling
- Sleeplessness
- A feeling of ringing in the ears.

Side effects with unknown frequencies:

- Being pale and feeling exhausted
- Confusion
- Hallucinations, depression
- Restlessness.
- Drowsiness
- Weird taste
- Blurred vision
- Photosensitivity.

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. 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 or by e-mail:

drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of ETIFLAM.

5. How to store ETIFLAM

Store all medicines out of reach of children.

Store at or below 30 °C. Store in the original package. Keep well closed.

6. Contents of the pack and other information

What ETIFLAM contains

The active substance is etoricoxib.

ETIFLAM 60: Each film-coated tablet contains etoricoxib 60 mg.

ETIFLAM 90: Each film-coated tablet contains etoricoxib 90 mg.

ETIFLAM 120: Each film-coated tablet contains etoricoxib 120 mg.

The other ingredients are anhydrous calcium hydrogen phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, opadry II white 39K590004 (ETIFLAM 60), and opadry II green 39K510004 (ETIFLAM 90 and ETIFLAM 120).

The film-coat is composed of hypromellose 15 mPas, hypromellose 50 mPas, lactose monohydrate, titanium dioxide and triacetin, iron oxide yellow* and indigo carmine*.

*Only applicable to ETIFLAM 90 and ETIFLAM 120.

What ETIFLAM looks like and contents of the pack

ETIFLAM 60:	White to off-white, apple shaped, biconvex film-coated tablet debossed with “C2” on one side and plain on the other side.
ETIFLAM 90:	Dark green, apple shaped, biconvex film-coated tablet debossed with “C3” on one side and plain on the other side.
ETIFLAM 120**:**	Dark green, apple shaped, biconvex film-coated tablet debossed with “C4” on one side and plain on the other side.

ETIFLAM film-coated tablets are packed in:

- Packs of 7’s in Alu/Alu blisters that are placed into an outer cardboard carton.
- Packs of 10’s in Alu/Alu blisters that are placed into an outer cardboard carton.
- Packs of 30’s in Alu/Alu blisters that are placed into an outer cardboard carton or in white HDPE bottles fitted with white child-resistant caps embossed with the instruction “TO OPEN PUSH DOWN AND TURN & CLOSE TIGHTLY”. The 30’s HDPE packs contain a 2 g silica gel desiccant.
- Packs of 90’s in white HDPE bottles fitted with white child-resistant caps embossed with the instruction “TO OPEN PUSH DOWN AND TURN & CLOSE TIGHTLY”. The 90’s HDPE packs contain a 1 g silica gel desiccant.
- The silica gel desiccant is made from a non-woven fabric bag and heat sealed along the edges with the manufacturer’s details printed in blue ink.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.