

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the pharmaceutical product:

ETOFLAM® GEL

(Etoricoxib, Linseed Oil, Methyl Salicylate & Menthol Gel)

2. Qualitative & Quantitative Composition:

ETOFLAM® GEL

Each gm gel contains:

Etoricoxib..... 10mg

Methyl Salicylate BP.....100mg

Menthol BP.....50mg

Linseed Oil BP..... 30mg

Gel base..... q.s.

(For the full list of excipients, see section 6.1)

3. Pharmaceutical form:

ETOFLAM® GEL

Semisolid preparation, gel

A white coloured gel.

4. Clinical particulars

4.1 Therapeutic indications

- Low back pain
- Joint pain
- Sprains and strains
- For quick relief from pain, Swelling, and inflammation
- It is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis.

4.2 Posology and method of administration

Posology

For Topical use only - This medication is for use on the skin only.

Do not apply near the eyes, mouth, nose or genitals, and be careful not to touch those areas while the medication is on your hands. If you do get the medication in those areas, flush with plenty of water. Wash your hand well before inserting contact lenses.

Apply a thin layer of medication to the affected area no more than 3 to 4 times a day. Rub in gently and thoroughly. After applying the medication, wash your hands unless you are using this medication to treat the hands. If treating the hands, wait at least 30 minutes after applying the medication to wash your hands.

Do not apply this medication to skin that is injured or irritated (e.g., cut, scraped, sunburned). Do not bandage or tightly wrap the affected area. Doing

so may increase the risk of side effects. You may cover the area loosely to protect clothing. Ask your pharmacist for more details.

Method of administration

ETOFLAM® GEL is for topical use only.

4.3 Contraindications

Children and adolescents under 16 years of age.

During the first 6 months of pregnancy, this medication should be used only when clearly needed. It is not recommended for use during the last 3 months of pregnancy due to possible harm to the unborn baby and problems with normal labor/delivery. Discuss the risks and benefits with your doctor.

4.4 Special warnings and precautions for use

Allergy – This medicine is not recommended for use in patients with a known allergy to etoricoxib or any other ingredients present along with it.

Do not apply near the eyes, mouth, nose or genitals, and be careful not to touch those areas while the medication is on your hands. If you do get the medication in those areas, flush with plenty of water. Wash your hand well before inserting contact lenses.

After applying the medication, wash your hands unless you are using this medication to treat the hands. If treating the hands, wait at least 30 minutes after applying the medication to wash your hands.

Do not apply this medication to skin that is injured or irritated (e.g., cut, scraped, sunburned). Do not bandage or tightly wrap the affected area. Doing so may increase the risk of side effects. You may cover the area loosely to protect clothing. Ask your pharmacist for more details.

4.5 Interaction with other medicinal products and other forms of interaction

- Topical corticosteroids or other topical analgesics: Concurrent use may increase the risk of skin irritation or other adverse reactions.
- Oral NSAIDs (e.g., ibuprofen, aspirin): Caution should be used when combining oral NSAIDs with this topical treatment due to the potential for additive systemic effects.
- Anticoagulants (e.g., warfarin): Monitor for any signs of bleeding as Methyl Salicylate has blood-thinning properties.

4.6 Fertility, Pregnancy and lactation

Pregnancy

During the first 6 months of pregnancy, this medication should be used only when clearly needed. It is not recommended for use during the last 3 months of pregnancy due to possible harm to the unborn baby and problems with normal labor/delivery. Discuss the risks and benefits with your doctor.

Breast feeding

It is not known whether etoricoxib is excreted in human milk. Etoricoxib is excreted in the milk of lactating rats. Women who use etoricoxib must not breast feed.

Fertility

The use of etoricoxib, as with any drug substance known to inhibit COX-2, is not recommended in women attempting to conceive.

4.7 Effects on ability to drive and use machines.

There is no influence on the ability to drive and use machines.

4.8 Undesirable effects

- Application site irritation/ burning sensation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>.

4.9 Overdose.

This medicine may be harmful if swallowed. If someone has overdosed and has serious symptoms such as passing out or trouble breathing.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids, coxibs,
ATC code: M01 AH05

Mechanism of Action

Etoricoxib is a selective cyclo-oxygenase-2 (COX-2) inhibitor within the clinical dose range.

Cyclooxygenase is responsible for generation of prostaglandins. Two isoforms, COX-1 and COX-2, have been identified. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain and inflammation. COX-2 is also involved in ovulation, implantation and closure of the ductus arteriosus, regulation of renal function, and central nervous system functions (fever induction, pain perception and cognitive function).

Linseed Oil is a plant-based oil which reduces swelling and improves blood circulation at the site of application. Additionally, it increases the penetration of Etoricoxib through the skin.

Menthol and Methyl Salicylate are topical analgesics (pain relievers). They work by first cooling the skin, then warming it up. This action further increases blood circulation and distracts from feeling the pain.

5.2 Pharmacokinetic properties

Absorption

It is absorbed through intact skin after topical administration and the amount absorbed is depending on the type of inflammation, vehicle used, area of skin

and the epidermal barrier. Absorption is increased in inflammation, occlusion and skin damage.

5.3 Preclinical safety data

None available

6. Pharmaceutical particulars

6.1 List of Excipients:

ETOFLAM® GEL

- Methyl Salicylate
- Menthol
- Carbomers
- Sorbitan Laurate
- Polysorbate (Tween 80)
- Sodium Hydroxide pellets
- Linseed oil
- Propylene Glycol
- Demineralized water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C. Protect from direct sunlight, heat and moisture.

6.5 Nature and contents of container

Etoflam® Gel is available in a pack of 50g and 30g lami tube.

6.6 Special precautions for disposal and other handling

Any unused medicine product or waste material should be disposed of in accordance with the local requirements.

7. Marketing authorization holder and manufacturing site addresses

Manufactured in India by:

Curis Lifesciences Ltd.

PF No-23, GIDC Industrial Estate,
Sanand-II, Ahmedabad-382110, Gujarat, India.

Manufactured For & Marketed by:

KRISHNA CHEMISTS LTD.

P.O. BOX 3328-00506
NAIROBI, KENYA.

8. Marketing Authorization Number

H2020/CTD5422/1719ER

9. Date of first registration/renewal of the registration

22/07/2026

10. Date of revision of the text

22/07/2026