1. Name of the medicinal product

ETOXYM GEL (S-ETODOLAC, LINSEED OIL, METHYL SALICYLATE, MENTHOL & CAMPHOR GEL)

2. Qualitative and quantitative composition

S-Etodolac……5%W/W

Virgin Linseed Oil BP…….3%W/W
Methyl Salicylate BP……5% W/W
Menthol BP 10%W/W
Camphor BP ..... 4% W/W
Excipients: Gel base..... Q.S.
Full list of excipients see section 6.1

3. Pharmaceutical form

GEL

Clear Colorless gel

4. Clinical particulars

4.1 Therapeutic indications

Etoxym Gel is used to treat fungal infections of the toenail, musculoskeletal aches and pain, inflammation, warts, and other conditions.

4.2 Posology and method of administration Posology

- Take a small quantity Etoxym gel on your palm
- Directly apply to the affected area.
- Gently rub the gel until it is evenly distribute.
- Use twice daily

Method of administration:

For topical use only

4.3 Contraindications

- Hypersensitivity to the any of active ingredients of this formulation.

4.4 Special warnings and precautions for use

- For external use only
- Avoid contact with eyes

- Keep out of the reach and sight of children
- Use under medical supervision

4.5 Interaction with other medicinal products and other forms of interaction

To date no drug interactions during treatment with Etoxym Gel have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy:

This product should be used during pregnancy only if the potential benefit justifies the potential risk.

Lactation:

This product should be used during breast feeding only if the potential benefit justifies the potential risk.

4.7 Effects on ability to drive and use machines

This product does not affects the ability of driving and using machines.

4.8 Undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Application site reactions
- Burning
- Irritation
- Itching and redness.

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 reaction to the National Regulatory Authority

4.9 Overdose

If you have accidentally apply too much Etoxym gel, or if someone else has apply your gel, wash the affected area with water.

5. Pharmacological properties

5.1 PHARMACODYNAMIC PROPERTIES

Mode of action

Etoxym Gel contains Etodolac, Linseed Oil, Methyl Salicylate, and Menthol. Non-steroidal anti-inflammatory drugs (NSAIDs) such as Etodolac and Menthol act by inhibiting the release of particular chemical messengers that cause pain and inflammation (redness and swelling). Linseed Oil is a plant-based oil that helps to reduce inflammation and increase blood flow at the application site. It also improves Etodolac penetration through the skin. On the skin, Methyl Salicylate has a cooling effect.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

The amount of Etoxym gel absorbed through the skin is proportional to the contact time and skin area covered with Etoxym gel, and depends on the total topical dose and the hydration of the skin. Distribution

Etoxym gel accumulates in the skin which acts as reservoir from where there is a sustained release of drug into underlying tissues. From there, Etoxym gel preferentially distributes and persists in deep inflamed tissues.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

As per dossier

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above

25°C. Do not freeze.

Store in the original package. Keep the container in

the outer carton. Keep out of reach children.

6.5 Nature and contents of container

30g in 1 Tube

6.6 Special precautions for disposal and other handling

No special requirements.

7. Manufactured By

CURIS LIFE SCIENCES PVT. LTD.

MAH HOLDER
KRISHNA CHEMISTS LTD
3rd Floor Metrix Hardware, Lusaka Road, Industrial Area.

8. Date of first authorisation/renewal of the authorisation
2025 July 17

9. Market Authorization Number
2646

10. Date of revision of the text
2030 July 17