Summary of Product Characteristics

1. Name of the medicinal product

ENZOFLAM GEL

2. Qualitative and quantitative composition

Each 30g lami tube contains;

Diclofenac Diethylamine BP ..... 1.16 % w/w

Eq. to Diclofenac Sodium BP.....1.00 % w/w

For full list of excipients, see section 6.1

3. Pharmaceutical form

A white to off white smooth topical gel.

4. Clinical particulars

4.1 Therapeutic Indications

Enzoflam Gel is indicated for the treatment of sprains, strains, bruises, soft tissue rheumatism. Enzoflam Gel is a warming non-staining, quick relief gel indicated in aches and pains of joints and muscles associated with arthritis, backaches, rheumatism, fibrositis, lumbago, sciatica, stiff neck, as a home treatment for stiff nose, aching feet, tennis elbow, rheumatic pain, bruises and chilblains.

4.2 Posology and Method of Administration

Direction: Approximately one inch band of Enzoflam Gel should be applied to the affected site three to four times daily with rubbing till the film disappears.

Route: For external application only.

4.3 Contraindications

Enzoflam Gel is contraindicated in patients who are hypersensitive to any of the component of gel formulation. Enzoflam Gel should not be applied to patients who have experienced asthma, acute rhinitis or urticaria, allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.

The use of Enzoflam Gel is contraindicated during the last trimester of pregnancy.

4.4 Special warnings and precautions for use

Patients should avoid taking a hot bath or shower just before or after applying gel, as it can enhance the burning sensation. It should not be allowed to come into contact with the eyes or mucous membranes. Tight bandages should not be applied on top of gel. Hands

should be washed immediately after application of gel unless hands and fingers are being treated. As with other NSAIDs, anaphylactoid reactions may occur in patients without prior exposure to diclofenac. Diclofenac sodium should be applied with caution to patients with the aspirin triad. The triad typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Diclofenac should not be applied to skin wounds, infections or exfoliative dermatitis.

This product should be used with caution in patients with a history of active gastrointestinal ulceration or bleeding, or reduced heart, liver or renal function, since isolated cases of systemic adverse reactions consisting of renal affection, has been reported with topically administered antiphlogistics .

It is known that NSAIDs can interfere with platelet function. Although the likelihood of systemic side effects is very low, caution should be used in patients with intracranial haemorrhage and blooding diathesis. Direct sunlight, including solarium, should be avoided during treatment If sensitivity skin reactions occur, discontinue use.

4.5 Interaction with other medicinal products and other forms of interaction

Systemic absorption of diclofenac from topical application is very low and no drug interactions during treatment with Enzoflam Gel have been reported, There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin. Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

4.6 Fertility, pregnancy and lactation

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Enzoflam should only be used during pregnancy or lactation when there is no safer alternative.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Occasionally local side effects such as skin rash, itching and reddening may be observed. In clinical studies, localized derminal side effects such as contact dermatitis, exfoliation, dry skin, and rash were found in patients treated with Enzoflam at a higher incidence than in those with placebo.

If severe dermal reactions occur, treatment with Enzoflam Gel may be interrupted until

the condition subsides.

Reporting of suspected adverse reactions: 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

Signs and symptoms

The low systemic absorption of topical Diclofenac renders overdosage extremely unlikely. In the event of accidental ingestion, resulting in significant systemic side-effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory drugs should be used.

Treatment Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from diclofenac overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoper fusion are probably.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical antirheumatics and

analgesics. ATC Code: MA01AB55

Mechanism of Action:

Diclofenac works by blocking the effect of chemicals called cyclo-oxygenase (COX) enzymes. These enzymes help to make other chemicals in the body, called prostaglandins. Some prostaglandins are produced at sites of injury or damage causing pain and inflammation. By blocking the effect of COX enzymes, fewer prostaglandins are produced, which means pain and inflammation are eased. The linseed oil helps in the penetration of the diclofenac through the skin. Methyl salicylate also acts as an analgesic and menthol gives relief due to its cooling effect.

5.2 Pharmacokinetic properties

When applied topically, diclofenac sodium, methyl salicylate linseed oil and menthol are absorbed and penetrate into the subcutaneous tissue, muscle tissue and joint.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of

excipients

Carbomer 934

Disodium

Edetate

Butylated Hydroxy Toluene

Propylene Glycol

Benzyl Alcohol

Isopropyl

Alcohol

Polyoxyl 40 Hydrogenated Castor Oil

Triethanolamine

Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30 C. Do not

freeze. Keep out of reach of children.

6.5 Nature and contents of container

The cream is filled into lami tube and packed in inner carton along with leaflet. Pack sizes available are 30g.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

Kremoint Pharma Pvt. Ltd.,

B-8 Additional MIDC,

Ambernath, Ambernath (E).

Thane 421506

8. Marketing authorisation number(s)

H2025/CTD9693/20334

9. Date of first authorisation/renewal of the authorisation

22/10/2024

10. Date of revision of the text

18th August 2026