

Generic Name: **Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel**

1.7.1. Summary of Product Characteristics

Summary of product characteristics is attached herewith.

1. Name of the medicinal product

ECOPAIN (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel)

2. Qualitative and quantitative composition

- Diclofenac Diethylamine BP (1.16 % W/W)
- Eq.to Diclofenac Sodium BP (1.00 % W/W)
- Linseed Oil BP (3.00 % W/W)
- Methyl Salicylate BP (10.00 % W/W)
- Menthol BP (5.00 % W/W)
- Gel Base (- QS)

3. Pharmaceutical form

Topical Gel

A white to off white smooth gel.

4. Clinical particulars

4.1 Therapeutic indications

ECOPAIN (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel) is indicated for the treatment of sprains, strains, bruises, soft tissue rheumatism. Diclofenac Sodium, Linseed Oil, Methyl Salicylate & Menthol 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.

4.4 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

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heart, liver or renal function, since isolated cases of systemic adverse reactions consisting of renal affection, has been reported with topically administered antiphlogistic.

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 **ECOPAIN** (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol 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, **ECOPAIN** (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel) 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 dermal side effects such as contact dermatitis, exfoliation, dry skin, and rash were found in patients treated with **ECOPAIN** (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel) at a higher incidence than in those with placebo.

If severe dermal reactions occur, treatment with **ECOPAIN** (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel) may be interrupted until the condition subsides.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical antirheumatics and analgesics.

ATC Code: MA01AB55

Diclofenac works by blocking the effect of chemicals called cyclo-oxygenase (COX) enzymes. These enzymes help to make other chemicals in the body, called

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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.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements

ADMINISTRATIVE DATA:

7. Marketing authorization holder

KREMOINT PHARMA PRIVATE LIMITED

B-8, Additional Ambernath, M.I.D.C.,

Ambernath (E), Dist. Thane – 421 506.

Tel (0251) 2620355 / 2620655 / 2620273

Email: info@kremointpharma.com

Website: www.kremointpharma.com

8. Marketing authorization number(s):

25-KD/171

9. Date of first authorization/renewal of the authorization

10. Date of revision of the text: Not Applicable

11. Legal status:

Prescription Only Medicine, POM