



1.3.1

Summary of Product Characteristics (SmPC)



Module-1 Administrative Information and Product Information

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate with menthol Gel

1.2 Strength

Composition:

Diclofenac Diethylamine BP	1.16% w/w
Eq. to Diclofenac Sodium	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	Q.S.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Diclofenac Diethylamine BP

Linseed Oil BP

Methyl Salicylate BP

Menthol BP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Label Claim (%W/W)	Function
1	Diclofenac Diethylamine e.q. to Diclofenac Sodium	BP	1.16 % Eq. to 1.00 %	Analgesic, Anti-inflammatory
2	Methyl Salicylate	BP	10.00	Counter Irritant
3	Menthol (Crystal)	BP	5.00	Counter Irritant
4	Virgin Linseed Oil	BP	3.00	Emollient
5	Sodium Methyl Hydroxybenzoate	BP	0.10	Preservative

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6	Sodium Propyl Hydroxybenzoate	BP	0.02	Preservative
7	Isopropyl Alcohol (IPA)	BP	6.66	Solvent
8	Butylated Hydroxyanisole	BP	0.05	Antioxidant
9	Polysorbate-80 (Tween-80)	BP	1.00	Wetting agent
10	Propylene Glycol	BP	3.33	Solvent
11	Carbomer 934P (Acrypol 934-P)	USP-NF	1.20	Gel base
12	Triethanolamine	BP	0.40	Alkalizing agent
13	Essence Fancy Floral SK 1251	IH	0.03	Fragrance
14	Butylated Hydroxytoulene	BP	0.10	Antioxidant
15	Propyl Gallate	BP	0.05	Antioxidant
16	Sodium Bisulphite	IH	0.20	Antioxidant
17	Isopropyl Myrisate	BP	2.00	Emollient
18	Disodium EDTA	BP	0.05	Chelating agent
19	Purified Water	BP	Q.S.	Vehicle

3. Pharmaceutical Form

Semi Solid Dosage Forms. Gel

White colour smooth gel filled in laminated tube.

4. Clinical Particulars

4.1 Therapeutic Indications

Relaxo Gel is used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles. It relieves rheumatic and muscular pain, and reduces swelling and inflammation, e.g., in injuries involving the tendons, ligaments, muscles and joints. For the relief of sprains, strains or bruises, backache, tendinitis (e.g., tennis elbow), and for localized and mild arthritis.



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4.2 Posology and Method of Administration

Adults and Adolescents over 12 years of age: Depending on the size of the painful area to be treated, 2-4 g (a circular shaped mass approximately 2.0-2.5cm in diameter) Relaxo Gel should be applied 3- 4 times daily to the affected sites and gently rubbed.

Duration of treatment depend on the indication and the patient's response. It is advisable to review the treatment after 2 weeks.

4.3 Contraindications

Hypersensitivity to Diclofenac, acetylsalicylic acid, isopropanol propylene glycol or other components of the gel base.

Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents (NSAIDs).

The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special Warnings and Special Precautions for Use

Relaxo Gel should be applied only to intact skin and or open wounds. It should not come into contact with the eyes or mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Systemic absorption of Relaxo Gel is low and hence the risk of an interaction is small. No drug interactions have been reported with Relaxo Gel to date

4.6 Fertility, Pregnancy and Lactation

Not Applicable.

4.7 Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects

Occasional skin rash, itching and redness of the skin

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4.9 Overdose

There has been no experience of overdose with Relaxo Gel.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Non-steroidal Anti-inflammatory and Analgesic

Diclofenac is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Diclofenac is a potent non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. It also has some uricosuric effect. Diclofenac inhibits cyclo-oxygenase activity with a reduction of production of prostaglandins in the tissue.

Linseed oil inhibits PGE₂, leukotriene, histamine and bradykinin induces inflammation. The oil also inhibited arachidonic acid-induced inflammation, suggesting its capacity to inhibit both cyclooxygenase and lipoxygenase pathway of arachidonate metabolism.

Methyl salicylate is applied topically as counter irritants for relief of pain associated with lumbago, sciatica, and rheumatic conditions.

Menthol, after topical application, causes a feeling of coolness due to stimulation of 'cold' receptors by inhibiting Ca⁺⁺ currents of neuronal membranes. It may also yield analgesic properties via kappa-opioid receptor agonism.

5.2 Pharmacokinetic Properties

When Relaxo Gel is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Diclofenac and its hydroxylated metabolites. After topical administration of Relaxo Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Sodium Methyl Hydroxybenzoate BP



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Sodium Propyl Hydroxybenzoate BP
Isopropyl Alcohol BP
Butylated Hydroxyanisole BP
Polysorbate-80 (Tween-80) BP
Propylene Glycol BP
Carbomer 934P (Acrypol 934-P) USP-NF
Triethanolamine BP
Essence Fancy Floral SK1251 IH
Butylated Hydroxytoluene BP
Propyl Gallate BP
Sodium Bisulphite BP
Isopropyl Myristate BP
Disodium Edetate BP
Purified Water BP

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30⁰C. Protect from light. Do not Freeze.

6.5 Nature and Contents of Container

White colour smooth gel filled in 30 gm laminated tube. Such 1 tube is packed in a printed carton along with the insert.

6.6 Special precaution for disposal and other handling

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



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7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

GENERICS AND SPECIALITIES LTD.

31, AWONIYI ELEM STREET,
OFF LATEEF SALAMI STREET.
AJAO ESTATE, LAGOS,
NIGERIA.

E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.

Telephone no.: +91-07949-135000

Fax: +91-07941-078062

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)



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Not Applicable

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MENTHOL GEL**