



Module-1 Administrative Information and Product Information

1. Name of the medicinal Product - Ritafenac Gel

Name of the medicinal Product - Ritafenac Gel

Diclofenac Diethylamine, Linseed Oil, Capsaicin with menthol Gel

Strength

Composition:

Diclofenac Diethylamine BP 1.16%w/w Eq. to

Diclofenac Sodium 1.00%w/w

Linseed Oil BP 3.00%w/w

Capsaicin USP 0.025% w/w

Menthol BP 5.00%w/w

Benzyle Alcohol BP 1.0%w/w

Gel Base Q.S.

2. Qualitative and Quantitative Composition

Qualitative Declaration Diclofenac

Diethylamine BP Linseed Oil BP

Capsaicin USP Menthol BP

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
3	Menthol	BP	5.00	Counter Irritant
4	Virgin Linseed Oil	BP	3.00	Emollient
5	S.M.P	BP	0.10	Preservative
6.	Capsaicin	USP	0.025	Counter irritant

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MENTHOL GEL



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6	S.P.P	BP	0.02	Preservative
7	Isopropyl Alcohol (IPA)	BP	6.66	Solvent
8	White Soft Parafen	BP	0.05	Antioxidant
9	Tween-80	BP	1.00	Wetting agent
10	Propylene Glycol	BP	3.33	Solvent
11	Carbomer 940	USP-NF	1.20	Gel base
12	Diethylamine	BP	0.40	Alkalizing agent
13	Essence Fancy Floral SK	IH	0.03	Fragrance
14	Benzyle Alcohol	BP	0.10	Antioxidant
15	Propyl Glycol	BP	0.05	Antioxidant
16	Light Liquid Parafen	IH	0.20	Antioxidant

Pharmaceutical Form

Semi Solid Dosage Forms. Gel

White colour smooth gel filled in laminated tube.

Clinical Particulars

Therapeutic Indications

Ritafenac 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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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.

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.

Special Warnings and Special Precautions for Use

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

Interaction with other medicinal products and other forms of interaction

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

Fertility, Pregnancy and Lactation

Not Applicable.

Effects on ability To Drive and use Machines

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

Undesirable Effects

Occasional skin rash, itching and redness of the skin

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Overdose

There has been no experience of overdose with Relaxo Gel.

3. Pharmacological Properties

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.

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.

Pharmacokinetic Properties

When Ritafenac 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 Ritafenac Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid.

Preclinical Safety Data

Not Applicable

4 Pharmaceutical Particulars

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

Incompatibilities

None.

Shelf Life

36 months

Special Precautions for Storage

Store below 30°C. Protect from light. Do not Freeze.

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.

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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5. PHARMACEUTICAL PARTICULARS

a. Incompatibilities

None known

Shelf life

36 months

Special precaution for storage

Store in cool, dry and dark place

b. Nature and contents of container

1 x 30g Tube

c. Special precautions for disposal <and other handling>

No special requirements.

d. APPLICANT/MANUFACTURER>

FANTASY DRUGS PVT LTD

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DICLOFENAC DIETHYLAMINE, LINSEED OIL, Capsaicin WITH MENTHOL GEL

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