SUMMARY OF PRODUCT CHARATERISTICS (SmPC)

1. Name of the medicinal Product – XFIT GEL

Name of the medicinal Product - Xfit Gel

Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate with menthol Gel

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

Benzyle Alcohol BP 1.0%w/w

Gel Base Q.S.

3. Qualitative and Quantitative Composition

Qualitative Declaration

Diclofenac Diethylamine BP

Linseed Oil BP

Methyl Salicylate BP

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
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

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

Pharmaceutical Form

Semi Solid Dosage Forms. Gel

White colour smooth gel filled in laminated tube.

4. Clinical Particulars

Therapeutic Indications

XFIT 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.

5. Posology and Method of Administration

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

Xfit 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

DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE WITH MENTHOL GEL

Module-1 Administrative Information and Product Information

Overdose

There has been no experience of overdose with Relaxo Gel.

6. 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 is 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 lipooxygenase 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.

Pharmacokinetic Properties

When Xfit 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\

6. Pharmaceutical Particulars

List of Excipients

Sodium Methyl Hydroxybenzoate BP

DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE WITH MENTHOL GEL

Module-1 Administrative Information and Product Information

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 30^0C. Protect from light. Do not Freeze.
KEEP OUT OF REACH OF CHILDREN

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.

DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE WITH MENTHOL GEL

7. Marketing authorization holder

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8. Marketing Authority

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