

1. Name of the Medicinal Product

(a) Product Name : FEXODEEP GEL

(b) Pharmaceutical Dosage Form : Gel

2. Quality and Quantitative Composition

(a) **Qualitative Declaration**, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

Composition:

Aceclofenac	BP	1.5% w/w
Methyl Salicylate	BP	10% w/w
Virgin Linseed Oil	BP	3% w/w
Menthol	USP	5% w/w
Capsaicin	USP	0.01% w/w
Gel base		q.s.

(b) **Quantitative Declaration**, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Spec	Label Claim	Overages (%)	Quantity (mg)	Batch Qty. Kg
1	Aceclofenac	BP	1.5%w/w	---	15	2.250
2	Methyl Salicylate	BP	10%w/w	---	100	15.000
3	Virgin Linseed Oil	BP	3%w/w	---	30	4.500
4	Menthol	USP	5%w/w	---	50	7.5000
5	Capsaicin	USP	0.01%w/w	---	0.1	0.300
6	Cabopol-934	BP	---	---	---	1.245
7	Benzyl Alcohol	BP	---	---	---	1.500
8	Tween-80	BP	---	---	---	4.500
9	DiEthylamine Salicylate	IHS	---	---	---	1.620
10	Propylene Glycol	BP	---	---	---	22.500
11	Purified Water	BP	---	---	---	q.s.

3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.:

Off white colour gel having characteristic odour.

4. Clinical Particulars

4.1 Therapeutic Indications:

Fexodeep 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.

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) Fexodeep 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 Aceclofenac, Methyl Salicylate, Linseed oil, Menthol 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 12 years is contraindicated.

4.4 Special warning and precautions for use:

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

4.5 Interaction with other medicinal products and other forms of interactions:

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

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machine:

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.

4.9 Overdose:

There has been no experience of overdose with Fexodeep Gel.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties:

Non-steroidal Anti-inflammatory and Analgesic

Aceclofenac is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Aceclofenac is a potent non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. It is also having some uricosuric effect. Aceclofenac inhibits cyclo-oxygenase activity with a reduction of production of prostaglandins in the tissue. Linseed oil inhibits PGE₂, leukotriene, histamine and bradykinin induce 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 F Gel is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Aceclofenac and its hydroxylated metabolites. After topical administration of Fexodeep Gel to hand and knee joints Aceclofenac can be measured in plasma, synovial tissue and synovial fluid.

5.3 Preclinical Safety Data:

Not Applicable.

6.0 Pharmaceutical Particulars

6.1 List of excipients:

Cabopol-980	BP
Benzyl Alcohol	BP
Tween-80	BP
Di-Ethylamine	IHS
Propylene Glycol	BP

6.2 Incompatibilities:

None.

6.3 Shelf life: 36 Months

6.4 Special precautions for storage:

Store protected from light and moisture, below 30°C. Do not freeze.

6.5 Nature and contents of container:

Off White colour gel having characteristic odour filled in 30 gm laminated tube. Such 1 tube is packed in a printed carton.

6.6 Instructions for use and handling

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

7.0 Marketing Authorization Holder

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