



1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

Diclofenac Sodium & Menthol Gel

2. Qualitative and Quantitative Composition

Composition:

Diclofenac Diethylamine BP.....1.16 w/w %

Equivalent to Diclofenac Sodium.....1.00 w/w %

Menthol BP.....2.0 w/w %

3. Pharmaceutical Form

Semi Solid Dosage Forms. Gel

4. Clinical Particulars

4.1 Therapeutic Indications

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) 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 advisable to review the treatment after 2 weeks.



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#### 4.3 Contraindications

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 Precautions for Use

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

#### 4.6 Pregnancy and Lactation

None.

#### 4.7 Effects on Ability to Drive and Use Machines

Not known.

#### 4.8 Undesirable Effects

Occasional skin rash, itching and redness of the skin.

#### 4.9 Overdose

There has been no experience of overdose with Gel.



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#### 5. Pharmacological Properties

##### 5.1 Pharmacodynamic 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 cyclooxygenase activity with a reduction of production of prostaglandins in the tissue.

##### 5.2 Pharmacokinetic Properties

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

##### 5.3 Preclinical Safety Data

Not known.



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6. Pharmaceutical Particulars

6.1 List of Excipients

Mineral Oil and White Ointment.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store in dry place at temperature below 30<sup>0</sup> C.

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 Precautions for Disposal and Other Handling

Not applicable.