Prescribing information (Summary of Product characteristics)

1. Name of the Medicinal Product

MUSCODAC GEL (Diclofenac Diethylamine, Linseed oil, Methyl Salicylate & Menthol Gel).

2. Qualitative and Quantitative Composition

Linseed Oil BP.....3.0 % w/w
Diclofenac Diethylamine BP.....1.16 % w/w
Methyl Salicylate USP .....10.0% w/w
Menthol USP.....5.0% w/w
Benzyl Alcohol (as preservative) .....1.0% w/w
Gel base .....q. s

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Topical gel for joint and muscular pain, anti- inflammatory preparations, non-steroids for topical use.

Product description:
White gel with characteristic odour of menthol.

4. Clinical Particulars

4.1. Therapeutic indications

For the local symptomatic relief of pain and inflammation in:
- Trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises
- Localised forms of soft tissue rheumatism

It is recommended that treatment be reviewed after 14 days in these indications.
For the treatment of osteoarthritis of superficial joints such as the knee.
In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks.

4.2. Posology and method of administration

Adults:

Muscodac Gel should be rubbed gently into the skin**.** Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3 - 4 times a daily. After application, the hands should be washed unless they are the site being treated.

Use in the elderly:

The usual adult dosage may be used.

Children:

Muscodac Gel is not recommended for use in children as dosage recommendations andindications for use in this group of patients have not been established.

Muscodac Gel is suitable for the transmission of ultrasound and may be used as a couplant in combination with ultrasound therapy. If large areas of the body are covered with gel, systemic absorption will be greater and the risk of side-effects increased, especially if the therapy is used frequently.

Mode of administration

Topical administration

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)

- Hypersensitivity to the active substance or any of the excipients,
- Hypersensitivity to propylene glycol, isopropanol or other components of the gel base.

4.4. Special warnings and precautions for use

Warnings:

The likelihood of systemic side effects with topical diclofenac is small compared to the frequency of side effects in patients using oral diclofenac. However, when Muscodac Gel is applied to relatively large areas of skin over a prolonged period of time, as described in the product information on systemic forms the possibility of systemic side effects cannot be excluded.

Muscodac Gel contains propylene glycol, which may cause mild, localised skin irritation in some people.

Precautions
Concomitant use of oral NSAID's should be cautioned as the incidence of untoward effects, particularly systemic side effects, may increase.

Muscodac Gel should not be co-administered with other products containing diclofenac. Muscodac Gel should be applied only to intact, non-diseased skin and not to skin wounds oropen injuries. It should be not used with occlusion. It should not be allowed to come into contact with the eyes or mucous membranes, and should never be taken by mouth.
Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

4.5. Interaction with other medicinal products and other forms of interaction
No evidence available

4.6. Pregnancy and lactation
No effects have been reported.

4.7. Effects on ability to drive and use machines
No evidence available

4.8. Undesirable effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: common (1/100, <1/10); uncommon (1/1,000, <1/100); rare (1/10,000, < 1/1,000); very rare (< 1/10,000, including isolated reports.

Table 1:

Infections and infestations:		
	Very rare:	Rash pustular.
Immune system disorders:-		
	Very rare cases:	Hypersensitivity, angioneurotic oedema.
Respiratory, thoracic and mediastinal disorders		
	Very rare:	Asthma.
Skin and subcutaneous tissue disorders		
	Common:	Rash, eczema, erythema, dermatitis (including dermatitis contact)
	Rare:	Dermatitis bullous
	Very rare cases:	Photosensitivity reactions (patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity

4.9. Overdose

The very low systemic absorption of the active components of the formulation when used externally makes overdose practically impossible. In case of accidental ingestion may develop systemic side effects. Treatment for ingestion: gastric lavage, induction of emesis, activated charcoal, forced diuresis, symptomatic therapy. Dialysis is ineffective because of the high degree of binding of diclofenac to plasma proteins (approximately 99%).

5. Pharmacological Properties

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Analgesic / Antipyretic / Anti-inflammatory (ATC code: M01AB55)

Diclofenac diethylamine is used topically as gel containing the equivalent to 1% of diclofenac sodium for local symptomatic relief of pain and inflammation. It is absorbed percutaneously.

A non -steroidal anti-inflammatory analgesic drug which inhibits prostaglandin synthesis by inhibition of cyclooxygenase (COX) thus reduces pain and inflammation.

Methyl Salicylate is a known anti-inflammatory agent. Methyl salicylate is a salicylic acid derivative that is an irritant to the skin and is used topically for the relief of pain in musculoskeletal, joint, and soft-tissue disorders.

Menthol when applied to an affected area in gel form, menthol rapidly cools tendons and muscles. Menthol primarily activates the cold-sensitive receptors in the skin. Menthol, after topical application, causes a feeling of coolness due to stimulation of 'cold' receptors by inhibiting Ca++ currents of neuronal membranes. Menthol is also a counter irritant and a mild analgesic. Menthol is a vasodialator; it dilates blood vessels, produces a feeling of coolness and produces analgesia.

Linseed Oil is a very rich source of Alpha-linolenic Acid (ALA) (an essential fatty acid). Incorporation of ALA and its metabolites in cell membranes can affect membrane fluidity

and may play a role in anti-inflammatory activity. Once ALA (which is different from arachidonic acid) is incorporated into cell membrane it produces eicosanoids (different types of chemicals than prostaglandins). The eicosanoids have anti-inflammatory properties.

5.2. Pharmacokinetic Properties
After cutaneous application of Diclofenac Sodium Gel, a rapid onset of Diclofenac absorption can be observed leading to measurable plasma levels as early as 30 minutes. The achieved systemic concentrations of diclofenac are about 50 times lower than those achieved followingoral administration of equivalent amounts of diclofenac.

5.3. Preclinical safety data

Pre-clinical effects were seen only at exposures which are extremely unlikely to cause concern for humans under normal conditions of use. Mutagenicity studies revealed no risks to man.

6. Pharmaceutical Particulars
6.1. List of excipients
Benzyl Alcohol USP
Carbopol 934 USP
Cremaphore RH 40 USP
Propylene Glycol USP
Citric Acid Monohydrate USP
Isopropyl Alcohol USP
Disodium Edetate USP
Diethylamine IH
Butylated Hydroxy Toluene USP
Purified Water BP

6.2. Incompatibilities
None stated

6.3. Shelf life
24 Months

6.4. Special precautions for storage
Store at below 30°C temperature.
Laminated Tubes: Store in the original package in order to protect from moisture and light.

6.5. Dosage forms and Packaging available

Nature and the contents of container: Aluminium laminated Tube containing 30 g gel packed in a carton along with pack insert.

6.6. Special precautions for disposal
Any product remaining at the end of treatment should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance withlocal requirements.

Wash your hands after application.

7. Manufacturer:
Indchemie Health Specialities Pvt Limited
Village – Thana, Tehsil-Baddi,
Dist. Solan, Himachal Pradesh – 173 205
H.O.: 510, Shah & Nahar Industrial Estate,
Dr. E. Moses Road, Worli-Mumbai 400018.
Maharashtra, India.

8. Marketing Authorization Number
TAN 22 HM 0032

9. Date of first Prequalification/ last renewal
10/01/2022

10. Date of Revision of the Text