SUMMARY OF PRODUCT CHARACTERISTICS

CAPSIFENAC GEL (Capsaicin / Diclofenac Diethylamine / Levomenthol / Methyl Salicylate Gel)

1. NAME OF THE MEDICINAL PRODUCT

CAPSIFENAC GEL (Capsaicin 0.025% w/w / Diclofenac Diethylamine 1.160% w/w / Levomenthol 1.000% w/w / Methyl Salicylate 3.000% w/w Topical Gel)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	Specification	Concentration
Capsaicin (as Capsicum Oleoresin)	USP	0.025% w/w
Diclofenac diethylamine	BP	1.160% w/w
Levomenthol	BP	1.000% w/w
Methyl salicylate	BP	3.000% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel (topical).

White to off-white coloured, semi-solid mass with a pungent odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CAPSIFENAC GEL is indicated for the relief of pain and inflammation associated with musculoskeletal disorders including sprains, strains, tendonitis, bursitis, head, neck and shoulder pain, sciatica, muscle stiffness, joint pain and backache in adults.

4.2 Posology and method of administration

Adults

Apply locally to the affected skin 3 to 4 times daily. The amount required depends on the size of the painful area; 2 to 4 g (a quantity ranging in size from a cherry to a walnut) is sufficient to apply to an area of approximately 400–800 cm². After application, the hands should be washed unless they are the site being treated. The duration of treatment depends on the indication and the response obtained. Treatment beyond 2 weeks is not recommended; therapy should be reviewed after this time.

Paediatric population

Dosage recommendations and indications for use in children have not been established. Keep out of the reach of children.

Method of administration

Topical application to intact skin only.

4.3 Contraindications

- Hypersensitivity to diclofenac, capsaicin, levomenthol, methyl salicylate, or to any of the excipients listed in section 6.1 (including propylene glycol and isopropyl alcohol).
- Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).

4.4 Special warnings and precautions for use

Application instructions

CAPSIFENAC GEL should be applied only to intact, healthy skin. It should not be applied to skin wounds, infections, exudative dermatoses or open injuries. It must not be allowed to come into contact with the eyes or mucous membranes, and must not be taken by mouth.

After application, patients should wash their hands thoroughly (unless the hands are the area being treated) to avoid inadvertent contact with the eyes or mucous membranes.

Duration of use

Treatment beyond 2 weeks is not recommended. If the condition worsens or symptoms persist for more than 2 weeks, or clear up and recur within a few days, the patient should discontinue use and consult a physician.

Systemic absorption

The likelihood of systemic side effects following topical diclofenac is small compared with oral diclofenac. However, when CAPSIFENAC GEL is applied to large areas of skin for prolonged periods, the possibility of systemic side effects cannot be excluded. In general, topical NSAIDs should be used with caution in patients with a history of (or active) gastro-intestinal ulceration or bleeding, or severe renal impairment.

Pregnancy — third trimester

Due to the NSAID content (diclofenac and methyl salicylate), CAPSIFENAC GEL is contraindicated from 30 weeks of pregnancy onward (see section 4.6).

Propylene glycol content

This product contains propylene glycol, which may cause skin irritation in some patients.

Isopropyl alcohol content

This product contains isopropyl alcohol, which may cause skin irritation and is flammable. Keep away from naked flames during and immediately after application.

4.5 Interaction with other medicinal products and other forms of interaction

Warfarin and anticoagulants:

The concurrent use of NSAIDs and warfarin has been associated with severe, sometimes fatal, haemorrhage. The exact mechanism is unknown but may involve enhanced bleeding from NSAID-induced gastrointestinal ulceration or an additive anticoagulant effect. Systemic reactions are unlikely when CAPSIFENAC GEL is used as recommended; nevertheless, the possibility of this interaction should be borne in mind, particularly if used on large skin areas.

Other NSAIDs and aspirin:

Topical diclofenac combined with other NSAIDs or high-dose aspirin increases the risk of gastrointestinal adverse events.

4.6 Fertility, pregnancy and lactation

Pregnancy

NSAIDs inhibit prostaglandin synthesis; when given during the latter part of pregnancy, they may cause premature closure of the foetal ductus arteriosus, foetal renal impairment, inhibition of platelet aggregation and delay of labour and birth. From 20 weeks of gestation, NSAID use may cause foetal renal dysfunction leading to oligohydramnios. Continuous treatment with NSAIDs during the last trimester should only be given on sound indications. From 30 weeks of gestation, NSAIDs including diclofenac should be avoided.

Safety of diclofenac in pregnancy has not been established; animal studies suggest reproductive toxicity at maternally toxic doses. Therefore, CAPSIFENAC GEL should not be used in pregnant women or those likely to become pregnant unless the expected benefits clearly outweigh the risk.

Breast-feeding

No measurable amounts of active substance are expected in the breast milk of nursing mothers following topical application at recommended doses. However, as no experience has been acquired with CAPSIFENAC GEL during lactation, it is not recommended for use in breast-feeding women.

Fertility

As with other NSAIDs, diclofenac may impair female fertility and is not recommended in women attempting to conceive.

4.7 Effects on ability to drive and use machines

Application of CAPSIFENAC GEL has not been found to have any effect on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

Local skin reactions are the most common adverse effects. Systemic reactions are rare when the product is used as recommended.

Category	Adverse Reaction
Local reactions (occasional)	Allergic or non-allergic contact dermatitis: itching, redness, oedema, papules, vesicles, bullae, scaling of the skin; burning sensation at application site (especially with capsaicin); initial transient stinging
Systemic reactions (isolated cases)	Generalised skin rash; hypersensitivity reactions (asthmatic attack, angioedema); photosensitivity reactions
Haemorrhagic events (very rare)	Severe haemorrhage associated with concurrent anticoagulant use (see section 4.5)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Topical application

The low systemic absorption from recommended use renders overdose by topical application extremely unlikely.

Accidental ingestion

In the event of accidental ingestion, general therapeutic measures for poisoning with non-steroidal anti-inflammatory drugs should be used. Management consists of supportive and symptomatic measures for complications such as hypotension, renal failure, convulsions, gastrointestinal irritation and respiratory depression. Methyl salicylate: ingestion of doses larger than 150 mg/kg can produce toxic symptoms (tinnitus, nausea, vomiting); serious toxicity occurs at >400 mg/kg (severe vomiting, hyperventilation, hyperthermia, confusion, coma, convulsions, acid-base disturbances). The average lethal dose for children is 10 ml (concentrated methyl salicylate). Treatment is supportive; gastric lavage and alkalinisation of urine may be considered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain — capsaicin and similar agents. ATC code: M02AB.

CAPSIFENAC GEL is an anti-inflammatory and analgesic preparation for external application. The pharmacological effects result from the combined pharmacodynamics of the four active substances.

Diclofenac diethylamine:

A potent, non-selective inhibitor of cyclooxygenase (COX-1 and COX-2, preferentially COX-2), reducing the formation of prostaglandins and leukotrienes from arachidonic acid. Diclofenac has both hydrophilic and hydrophobic properties enabling good skin penetration. Diclofenac diethylamine (the diethylammonium salt) has been shown effective in the short-term management of musculoskeletal disorders.

Capsaicin:

The major pungent principle of Capsicum species. Capsaicin renders the applied area insensitive to pain by depleting substance P, a neuropeptide that transmits pain impulses from peripheral neurons to the CNS. Pain relief is obtained after substance P is substantially depleted. It acts as a counter-irritant topical analgesic.

Levomenthol:

An alcohol obtained from diverse mint oils. At low concentrations it stimulates sensory nerve endings for cold, causing a sensation of coolness and a local analgesic effect. Levomenthol has been shown to enhance skin penetration of methyl salicylate and to inhibit in vivo and in vitro hydrolysis of methyl salicylate to salicylic acid.

Methyl salicylate:

A counter-irritant that is rapidly hydrolysed by skin esterases to release salicylate in the epidermis and dermis. Methyl salicylate produces a paradoxical pain-relieving effect by generating a sensation that counters more intense pain (gate control theory).

5.2 Pharmacokinetic properties

Diclofenac — Absorption

When applied locally, diclofenac is absorbed through the skin. The amount absorbed is proportional to the contact time and skin area and depends on the total topical dose and skin hydration. Absorption amounts to approximately 6% of the dose after topical application of 2.5 g gel per 500 cm² skin (determined by reference to total renal elimination vs oral diclofenac). Occlusion over 10 hours leads to a three-fold increase in absorption. Maximum plasma concentrations of diclofenac after topical administration are approximately 100 times lower than after oral administration.

Diclofenac — Distribution

After topical administration to hand and knee joints, diclofenac can be measured in plasma, synovial tissue and synovial fluid. 99.7% of diclofenac binds to serum proteins, chiefly albumin (99.4%).

Diclofenac — Biotransformation

Biotransformation of diclofenac involves glucuronidation of the intact molecule, and single and multiple hydroxylation resulting in phenolic metabolites, most of which are converted to glucuronide conjugates. Two phenolic metabolites are biologically active (but to a much smaller extent than diclofenac). Metabolism following percutaneous and oral administration is similar.

Diclofenac — Elimination

Total systemic clearance from plasma is 263 ± 56 mL/min. Terminal plasma half-life is 1–2 hours. Diclofenac and its metabolites are excreted mainly in the urine. No accumulation is expected in patients with renal impairment. In patients with chronic hepatitis or non-decompensated cirrhosis, kinetics and metabolism are the same as in patients without liver disease.

5.3 Preclinical safety data

Diclofenac:

Genotoxicity studies with diclofenac sodium did not show any evidence of genotoxic or mutagenic potential. Three previous long-term carcinogenicity studies in rats and mice with diclofenac sodium did not suggest any potential to induce tumours. No reproductive or developmental toxicity studies were conducted with diclofenac diethylamine; however, reproductive toxicity studies with diclofenac sodium (pre-ICH design Segments I–III in rats and mice, rats and rabbits) revealed no evidence of teratogenicity, although foetal toxicity was observed at maternally toxic doses.

Capsaicin:

Not generally recognised as safe and effective by the US FDA for fever blister treatment but is considered safe and effective as an external analgesic counterirritant at recommended concentrations.

Methyl salicylate:

Methyl salicylate is teratogenic in animals at high systemic doses. Topical application at recommended concentrations in CAPSIFENAC GEL results in plasma salicylate levels far below toxic levels. No mutagenic activity was detected at doses up to 5,000 µg/plate in bacterial assay studies. The product did not present teratogenic hazard in petroleum-based grease/methyl salicylate tests in rats at doses up to 6 g/kg/day. Percutaneous absorption from this formulation is insufficient to cause systemic reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol, Carbomer 940, propylene glycol, isopropyl alcohol, Polysorbate 80, disodium edetate, sodium hydroxide, purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months. Keep the tube tightly closed after use.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light. Do not freeze. Keep the tube tightly closed after use. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Tube of 10 g or 20 g, packed in a carton with package insert.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

PRISMA PHARMA FZE (Applicant/Supplier)

P.O. Box 17269,

Jebel Ali Free Zone, Dubai, United Arab Emirates.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

19799/R1

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

07.02.2026

10. DATE OF REVISION OF THE TEXT

07.02.2026