

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of the medicinal product

Power Heat (Methyl Salicylate Bp 15.00 % W/W, Menthol Bp 10.00 % W/W, Turpentine Oil Bp 2.00 % W/W, Eucalyptus Oil Bp 2.00 % W/W Camphor Bp 3.00 % W/W Cream)

2. Qualitative and quantitative composition

Each Tube contains:

Methyl Salicylate BP.....	15.00 % W/W
Menthol BP.....	10.00 % W/W
Turpentine Oil BP	2.00 % W/W
Eucalyptus Oil BP	2.00 % W/W
Camphor BP	3.00 % W/W
Cream Base.....	Q.S.

For the full list of excipients see section 6.1

3. Pharmaceutical form

Cream

White to off-white smooth cream.

4. Clinical particulars

4.1 Therapeutic Indications

Power Heat Cream is an extra strong combination of proven medicaments can be used topically for:

- Symptomatic relief of aches, muscular pains & stiffness Pain of joints and muscles.
- Conditions like arthritis, backaches, sprains, lumbago, fibrositis and sciatica.

4.2 Posology and Method of Administration

Gently massage Power Heat Cream into the affected area till it is completely absorbed by the Skin. Do not use the cream on open area or wound. Apply 2-3 times daily or as and when necessary. Or as Directed by the Physician.

4.3 Contraindications

Power Heat Cream is contraindicated for use in the following:

- Patients having delirium

- Muscle twitching epileptiform convulsion
- Depression of the central nervous system
- Patients having hepatic disorders

4.4 Special warnings and precautions for use

Power Heat is dangerous to place cream into the nostrils of an infant as use is not recommended for children below 5 years of age. A small quantity applied in this way may cause immediate collapse. Do not apply on broken or sensitive areas of skin. Wash hands thoroughly after use. Discontinue use if excessive irritation occurs. If symptoms persists consult your Physician.

4.5 Interaction with other medicinal products and other forms of interaction

Excessive application concomitantly with NSAIDs should be avoided as this may increase side effects. There is an increased risk of bleeding due to its antiplatelet effects. There may be an enhancement of phenytoin or valproate effect with excessive use due to the methyl salicylate content.

4.6 Fertility, pregnancy and lactation

In the absence of sufficient data the use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Local application to the nostrils may cause apnoea. Contents of the cream may cause irritation and absorption of large Amounts may cause local burning.

Reporting of adverse Effects

Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdose

No cases of overdose have been reported.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical product for Joint and Muscular Pain, Preparations with acid salicylic derivative.

ATC code: M02AC

Camphor: Counter irritant and mild analgesic when used topically.

Menthol: Cooling and analgesic when used topically.

Eucalyptus Oil: Counter irritant and mild analgesic when used topically.

Methyl Salicylate: Has analgesic properties. It is readily absorbed through the skin and relieves pain in rheumatic conditions.

Turpentine Oil: Rubefacient when used topically.

5.2 Pharmacokinetic properties

When applied topically Methyl Salicylate, Menthol, Turpentine Oil, Eucalyptus Oil & Camphor are absorbed and penetrate into the subcutaneous tissue, muscle tissue and joint .

5.3 Preclinical safety data

Methyl Salicylate: Methyl Salicylate toxicity is as for aspirin. Problems may include hypersensitivity resulting from skin eruptions. Salicylates have been shown to cross the placenta and have shown teratogenicity in animals. Salicylates are also believed to be implicated in the onset of Reyes Syndrome in children.

Menthol: Menthol may give rise to hypersensitivity reactions including contact dermatitis. Cases of toxicity have been reported following ingestion or application to the nostrils. With Gonne Balm, it would be very unlikely that an amount likely to cause toxicity problems could be ingested or inhaled.

Turpentine Oil: Turpentine Oil toxicity usually arises from ingestion though some symptoms can appear after skin absorption of large amounts. Hypersensitivity reactions and local irritation have been reported.

Eucalyptus Oil: Eucalyptus Oil toxicity usually arises from ingestion, particularly in children. If used in accordance with the directions then problems are unlikely.

Camphor: Camphor toxicity usually arises from ingestion, particularly in children. If used in accordance with the directions then problems are unlikely.

6. Pharmaceutical particulars

6.1 List of excipients

Cetostearyl Alcohol
Cetomacrogol 1000
Propylene Glycol
Anhydrous Lanolin
Methyl Paraben
Propyl Paraben
Carbomer 940
Sodium Hydroxide
Polyoxyl 40 Hydrogenated Castor Oil
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30 C. Do not freeze.
Keep out of reach of children.

6.5 Nature and contents of container

The cream is filled into lami tube and packed in inner carton along with leaflet.
Pack sizes available are 20g.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

Kremoint Pharma Pvt. Ltd.,
B-8 Additional MIDC, Ambernath,
Ambarnath (E). Thane 421506

8. Marketing authorisation number(s)

H2022/CTD8595/16855

9. Date of first authorisation/renewal of the authorisation

05/08/2023

10. Date of revision of the text

05/08/2023