

Summary of Product Characteristics

1. Name of the medicinal product

POWER HEAT PLUS

2. Qualitative and quantitative composition

Diclofenac Diethylamine BP1.16 %w/w
Eq. to Diclofenac Sodium BP..... 1.00 % w/w
Linseed Oil BP.....3.00 % w/w
Methyl Salicylate BP.....10.00 % w/w
Menthol BP5.00 % w/w
Capsaicin USP.....0.025 %
w/w Gel base.....Q.S.

For the full list of excipients see section 6.1

3. Pharmaceutical form

Gel

4. Clinical particulars

4.1 Therapeutic Indications

Power Heat Plus is a topical non-staining analgesic gel indicated for:

- Aches and pain of joints.
- Muscles pain associated with arthritis, backaches, sprain fibrositis and sciatica.
- Power Heat Plus is irritant to skin and is used topically as rubefacient preparations in musculoskeletal joint and soft tissue disorders and for minor peripheral vascular such as chilblains.
- Relieve local pains and headache an in rheumatic affections. The diethylammonium salt of diclofenac is used topically as a gel containing the equivalent of 1 % of diclofenac sodium for the local symptomatic relief of pain and inflammation; it is applied to the

affected site 3 to 4 times daily; treatment should be reviewed after 14 days or after 28 days if used for osteoarthritis.

4.2 Posology and Method of Administration

It is applied to affected site 3 to 4 times daily; treatment should be reviewed after 14 days or after 28 days if used for osteoarthritis. Or as prescribed by Physician.

4.3 Contraindications

Power Heat Plus is contraindicated in individuals with known history of sensitivity or allergic reactions to this product or any of its ingredients.

4.4 Special warnings and precautions for use

Apply by gentle massage only. Avoid contact with eyes, mucous membrane and inflamed or broken skin, discontinue if rash develops. Hands should be washed immediately after use. Not for use with occlusive dressing. Topical application of large amount may result in systemic effects including hypersensitivity and asthma (renal disease has also been reported).

4.5 Interaction with other medicinal products and other forms of interaction

Systemic absorption of diclofenac from topical application is very low and no drug interactions during treatment with Power Heat Plus have been reported.

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin.

Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

4.6 Fertility, pregnancy and lactation

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Radian B Muscle Rub should only be used during pregnancy or lactation when there is no safer alternative.

4.7 Effects on ability to drive and use

machines Not applicable.

4.8 Undesirable effects

Self-limiting skin reactions such as rash or pruritus may occur. More serious skin reactions attributed to Power Heat Plus include bullous dermatitis and erythema multiform.

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 <https://pv.pharmacyboardkenya.org>

4.9 Overdose

Due to the low systemic absorption of topically applied POWER HEAT PLUS overdosage is unlikely. If the patient shows signs of overdosage, the skin surface may be flushed with water immediately and dried. Seek medical care immediately. If accidentally induce vomiting, call a physician.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug

ATC code: M02AB

POWER HEAT PLUS is an off -white to light peach coloured smooth gel which incorporates Diclofenac Diethylamine, Linseed Oil, methyl salicylate, menthol and Capsaicin as active ingredients.

Diclofenac Diethylamine is a nonsteroidal anti-inflammatory drug. Linseed Oil also having a anti-inflammatory property. Methyl salicylate has the actions of the salicylates. Menthol relieves itching, dilates the vessels causing a sensation of coldness followed by an analgesic effect. It is readily absorbed through the skin and has counter-irritant properties. Capsaicin has counter-irritant properties

5.2 Pharmacokinetic properties

The anti-inflammatory effects of diclofenac are believed to be due to inhibition of both leukocyte migration and the enzyme cyclooxygenase (COX-1 and COX-2), leading to the peripheral inhibition of prostaglandin synthesis. As prostaglandins sensitize pain receptors, inhibition of their synthesis is responsible for the analgesic effects of diclofenac. Antipyretic effects may be due to action on the hypothalamus, resulting in peripheral dilation, increased cutaneous blood flow, and subsequent heat dissipation.

Methyl salicylate is absorbed through the skin. It is rapidly hydrolysed to salicylic acid, mainly in the liver and excreted, mainly by the kidney, as salicylic acid, as salicyluric acid, as salicylic phenolic and acyl glucuronide, and as gentisic acid. The excretion is pH dependent with up to 30% being excreted as salicylic acid under alkaline conditions and as low as 2% under acid conditions. The plasma half- life of salicylates is 2-3 hours.

5.3 Preclinical safety

data Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Carbomer 934

Disodium Edetate

Butylated Hydroxy Toluene

Propylene Glycol

Benzyl Alcohol

Isopropyl Alcohol

Polyoxyl 40 Hydrogenated Castor Oil

Triethanolamine

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

A Lami tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex end seal band in the crimp seal and a white plastic cap for reclosure after piercing membrane.

Pack sizes: The cream is filled into lami tubes with white colour stand-up caps and enclosed in an outer carton. Pack sizes available are 15Gm, 20 Gm, 25Gm, 30Gm, & 50Gm.

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,
Ambernath (E). Thane 421506

8. Marketing authorisation number(s)

H2022/CTD9354/20563

9. Date of first authorisation/renewal of the authorisation

07/08/2023

10. Date of revision of the text

18/08/2026