1.3 Product Information

1.3.1 Summary of product characteristics (SmPC)

Enclosed-

National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

DICLOFENAC DIETHYLAMINE, METHYL SALICYLATE, MENTHOL AND LINSEED OIL GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Diclofenac Diethylamine BP	1.16%w/w
(Equivalent to Diclofenac Sodium	1.00 % w/w)
Methyl Salicylate BP	10.00 % w/w
Menthol BP	5.00 %w/w
Linseed Oil BP	3.00 %w/w
Preservative Benzyl Alcohol BP	1.00 %w/w
Gel base	q.s

3. PHARMACEUTICAL FORM

Gel

4. Clinical particulars

4.1 Therapeutic indications

Diseases of the locomotor system: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis, osteoarthrosis of peripheral joints and spinal column, osteochondrosis with radicular syndrome, sciatica);

- rheumatic damage to soft tissues (tenosynovitis, bursitis);
- muscular pain of rheumatic or non-rheumatic origin;
- traumatic damage to soft tissues (due to sprains, bruises).

4.2 Posology and method of administration

Adults and children over 12 years: apply the formulation on the skin 3-4 times in a day and rub in gently. The quantity of formulation to be used depends upon the size of the painful area. A single dose is 2-4 g (4-8 cm when the tube neck is fully open). Children from 6 to 12 years old to apply no more than 2 times a day, a single dose of 2 grams.

The duration of treatment without consulting a physician should not exceed 10 days.

The possibility of a long-term use of medicine the doctor decides individually.

Method of administration

For external use.

4.3 Contraindications

Hypersensitivity to diclofenac, methyl salicylate or other components of the formulation, acetylsalicylic acid or other NSAIDs, aspirin "asthma", pregnancy (third trimester), lactation period,

children below 6 years, broken skin.

4.4 Special warnings and precautions for use

DICLOSEED GEL should be applied only on unbroken skin and not on open wounds. Occlusive dressing is not recommended after application. Care should be taken to avoid contact with the eyes and mucous membranes. ®

Use with caution in: severe disorders of the liver and kidney functions, bronchial asthma, pregnancy (first and second trimesters), elderly patients.

4.5 Interaction with other medicinal products and other forms of interaction

Diclofenac may potentiate the action of drugs which induce photo sensitisation. Clinically significant interactions with other drugs have not been reported.

4.6 Pregnancy and Lactation

This formulation should not be used in the third trimester of pregnancy. The question of use of the drug in first and second trimesters of pregnancy is solved individually. Due to the lack of experience of using drug during lactation, its use in this period is not recommended.

4.7 Effects on ability to drive and use machines

The drug does not adversely affect the ability to drive vehicles and other potentially dangerous machinery.

4.8 Undesirable effects

Local reactions: eczema, photosensitisation, contact dermatitis (itching, redness, oedema of treated area of skin, papules, vesicles, peeling).

Systemic reactions: generalised skin rash, allergic reactions (urticaria, Quincke's (angioneurotic) oedema, bronchospastic reactions).

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 Pharmacodynamics properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug (NSAID)

The pharmacological action of the formulation is based on the ingredients. It has a local analgesic, anti-inflammatory and anti-o edematous action. Diclofenac sodium and methyl salicylate are non-steroidal anti-inflammatory drugs with a pharmacological action based on the ability to inhibit synthesis of prostaglandins. When used locally, diclofenac and methyl salicylate are rapidly absorbed, penetrate into the subcutaneous fat, muscular tissue and joint capsule, reduce pain and inflammation in the joints, morning stiffness and swelling of joints, facilitate increase in the extent of movements. The main component of linseed oil is α-linolenic acid which has an anti-inflammatory action. Menthol induces irritation of nerve endings and has a local distracting and mild analgesic action, besides inducing a cooling sensation.

5.2 Pharmacokinetic properties

When applied topically, diclofenac sodium, methyl salicylate and linseed oil are absorbed and penetrate into the subcutaneous tissue, muscle tissue and joint capsule.

5.3 Preclinical safety data

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 956
Propylene Glycol
Sodium lauryl Sulphate
Emulsifing wax
Cetosteryl alcohol
Sodium Hydroxide
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special precautions for storage

Store in a Cool Place. Do not freeze

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

30 gm Collapsible Lami Tube

6.6 Special precautions for disposal <and other handling>

No special requirements.

7.0 APPLICANT/MANUFACTURER

Health Care Formulations Pvt. Ltd.
C/8, Sardar Estate, Ajwa Road
Vadodara-390019, Gujarat.

Manufacturer:
Health Care Formulations Pvt. Ltd.
C/8, Sardar Estate, Ajwa Road
Vadodara-390019, Gujarat.