MYONAC GEL (Aceclofenac, Methyl salicylate, Linseed oil, Capsaicin and Menthol gel)

Summary of Product Characteristics

1. Name of the medicinal product

MYONAC GEL (Aceclofenac, Methyl salicylate, Virgin Linseed oil, Capsaicin and Menthol)

2. Qualitative and quantitative composition

Composition:

Aceclofenac BP 1.5% w/w

Methyl salicylate BP 10% w/w

Virgin Linseed oil BP 3% w/w

Capsaicin USP 0.01% w/w

Menthol USP 5% w/w

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Semi Solid Dosage Form. Gel, white colour smooth gel filled in laminated tube.

4. Clinical particulars

4.1 Therapeutic indications

Myonac Gel is used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles. It relieves rheumatic and muscular pain, and reduces swelling and inflammation, e.g., in injuries involving the tendons, ligaments, muscles and joints. For the relief of sprains, strains or bruises, backache, tendinitis (e.g., tennis elbow), and for localized and mild arthritis.

4.2 Posology and method of administration

Adults and Adolescents over 12 years of age: Depending on the size of the painful area to be treated, 2-4 g (a circular shaped mass approximately 2.0-2.5cm in diameter) Myonac Gel should be applied 3-4 times daily to the affected sites and gently rubbed. Duration of treatment depends on the indication and the patient's response. It is advisable to review the treatment after 2 weeks.

4.3 Contraindications

Hypersensitivity to Aceclofenac, acetylsalicylic acid, isopropanol propylene glycol or other components of the gel base. 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). The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warnings and precautions for use

Myonac Gel should be applied only to intact skin and/or open wounds. It should not come into contact with the eyes or mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Systemic absorption of Myonac Gel is low and hence the risk of an interaction is small. No drug interactions have been reported with Myonac Gel to date.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on the ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Occasional skin rash, itching and redness of the skin.

4.9 Overdose

There has been no experience of overdose with Myonac Gel.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Non-steroidal Anti-inflammatory and Analgesic Aceclofenac is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Aceclofenac is a potent non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. It also has some uricosuric effect. Aceclofenac inhibits cyclo-oxygenase activity with a reduction of production of prostaglandins in the tissue. Linseed oil inhibits PGE2, leukotriene, histamine and bradykinin induces inflammation. The oil also inhibited arachidonic acid-induced inflammation, suggesting its capacity to inhibit both cyclooxygenase and lipooxygenase pathway of arachidonate metabolism. Methyl salicylate is applied topically as counter irritant for relief of pain associated with lumbago, sciatica, and rheumatic conditions. Menthol, after topical application, causes a feeling of coolness due to stimulation of ‘cold’ receptors by inhibiting Ca++

currents of neuronal membranes. It may also yield analgesic properties via kappa-opioid receptor agonism.

5.2 Pharmacokinetic properties

When Myonac Gel is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Aceclofenac and its hydroxylated metabolites. After topical administration of Myonac Gel to hand and knee joints, Aceclofenac can be measured in plasma, synovial tissue and synovial fluid.

5.3 Preclinical safety data

Not Applicable.

6. Pharmaceutical particulars

6.1 List of excipients

No.	Excipient	Specification
1	Aceclofenac	BP
2	Methyl salicylate	BP
3	Menthol	BP
4	Capsaicin	BP
5	Linseed oil	BP
6	Propylene glycol	BP
7	Carbopal 934	BP
8	Triethanolamine	BP
9	Hard Liquid Paraffin	BP
10	Cetomacrogol -1000	BP
11	White Soft Paraffin	BP
12	Cetostearyl alcohol	BP
13	Purified water	BP

6.2 Incompatibilities

Nil.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in dry place below 30°C. Protect from light.

6.5 Nature and contents of container

30 gms gel filled in laminated tube sealed and packed in a carton with package insert.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder & imported by

WIN PHARMA LTD.,

P.O. BOX-2482-00200, NAIROBI, KENYA

8. Marketing authorisation number

H2024/CTD10675/23921

9. Date of first authorisation/renewal of the authorisation

2024 September 15

10. Date of revision of text

2024 September 15