

## RHEUMAC<sup>®</sup> DICLOFENAC GEL 1% W/W

### COMPOSITION:

#### Each gram contains:

Diclofenac diethylamine BP equivalent to Diclofenac Sodium 10mg. Excipients.....q.s.

Excipients: Carbopol 934, Mono Propylene Glycol, Rectified Spirit,

Poly Ethylene Glycol (PEG 400), Glycerin, Sodium Sulphite, Lavender Flavour Essence.

### INDICATIONS:

**Rheumac<sup>®</sup>** Gel is applied topically to relieve pain and inflammation in localized forms of soft-tissue rheumatism e.g. tendonitis, shoulder-hand syndrome and bursitis. It is indicated in case of localized rheumatic disease e.g. osteoarthritis of peripheral joints and of the vertebral column and periarthropathy. **Rheumac<sup>®</sup>** Gel affords effective relief from tenderness and pain on movement, in addition to providing a soothing and cooling effect on affected parts. In the presence of inflammation of traumatic or rheumatic origin the anti-inflammatory and analgesic properties of **Rheumac<sup>®</sup>** Gel elicit a clinical response characterized by a decrease in inflammatory swelling.

### METHOD OF APPLICATION AND DOSAGE:

**Rheumac<sup>®</sup>** Gel is applied topically by gently rubbing it on the affected parts. It is applied 3-4 times daily on the affected sites or as directed by the physician. Treatment should be reviewed after 14 days. **Rheumac<sup>®</sup>** Gel can also be employed as an accompanying treatment together with other dosage forms of **Rheumac<sup>®</sup>** preparations such as **Rheumac<sup>®</sup>** enteric coated tablets. **Rheumac<sup>®</sup>** Gel combines the essential anti-inflammatory and analgesic properties of diclofenac with the ease of application and comfort of gel formulation making it safe, fine and suitable for topical application.

### PRECAUTIONS, CONTRAINDICATIONS, WARNINGS AND SIDE EFFECTS:

1. **Rheumac<sup>®</sup>** Gel should be applied only to intact skin surface and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or with mucous membranes.

2. **Rheumac<sup>®</sup>** Gel is contraindicated in patients with known hypersensitivity to diclofenac, acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (NSAID's) in addition to isopropanol or propylene glycol.

3. The side-effects which may occasionally occur following **Rheumac<sup>®</sup>** Gel medication include itching, reddening and out break of a skin rash, etc. Repeated and prolonged application of **Rheumac<sup>®</sup>** Gel over relatively large areas of skin may result in systemic side effects.

### PHARMACOLOGY:

**Rheumac<sup>®</sup>** Gel contains Diclofenac which is a non-steroidal anti-inflammatory agent with anti-inflammatory and analgesic properties. It exerts its anti-inflammatory effect by inhibiting cyclo-oxygenase enzyme which is involved in the biosynthesis of prostaglandins. The analgesic effect of **Rheumac<sup>®</sup>** Gel is due to its action at pain receptors and also as a consequence of its anti-inflammatory potency. The acute anti-inflammatory effect is evident as reduction of vasodilation and reduction of increased vascular permeability. The oedema formation is reduced, as is cellular participation in the inflammatory process.

On topical application of **Rheumac<sup>®</sup>** Gel Diclofenac penetrates the skin and accumulates in the underlying tissue, thus combating both acute and chronic inflammatory reactions. Patients with rheumatoid arthritis who are receiving repeated treatment with this preparation have higher concentration of the drug in the synovial fluid and synovial tissue compared with plasma thus confirming that diclofenac penetrates into the inflamed zone following local application.

The amount of diclofenac absorbed through the skin following topical application as compared to oral administration of diclofenac sodium coated tablets is approximately 6% of the dose applied.

**LEGAL CATEGORY:** Prescription Only Medicine (POM).

**THERAPEUTIC CATEGORY:** ATC: M02A (Topical product for joint muscular pain)

**STORAGE CONDITIONS:** Store in a dry place below 30°C. maintain air tight closure. Do not Freeze. Protect from light. Keep all medicines out of reach of children.

**SHELF LIFE:** As per the product label.

### PRESENTATION:

**Rheumac<sup>®</sup>** Gel presented as a clear gel packed in 20g and 30g collapsible tubes.

**Date of Review :** September 2017

**LICENSE HOLDER:** LABORATORY & ALLIED LTD.



Manufactured by:

**Laboratory & Allied Ltd.**

Plot No. 209/10349, Mombasa Road,  
P.O. Box 42875, Nairobi, Kenya

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