1.4 PRODUCT INFORMATION.
1.4.1 Prescribing information (Summary of Product Characteristics)
1. Name of the Medicinal Product:
Rheumac Gel

2. Qualitative and Quantitative composition:
The gel contains: Diclofenac dimethylamine equivalent to 1%w/w of Diclofenac Sodium BP and excipients are provided in section 6.1

3. Pharmaceutical form:
Topical Gel
A clear translucent gel. Packed in 20g tubes and contained in a unit box with literature insert.

4. Clinical particulars.
4.1 Therapeutic indication:
Rheumac Gel is applied topically to relieve pain and inflammation in localized forms of soft-tissue rheumatism e.g tendovaginitis, shoulder-hand syndrome and bursitis. It is indicated in case of localized rheumatic diseases e.g osteoarthrosis of peripheral joints and of the vertebral column and periathropathy. Rheumac 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 gel elicit a clinical response characterized by a decrease in inflammatory swelling.

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

4.3 Contraindication:
Rheumac 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.

4.4 Special warning and precaution for use:
Rheumac Gel should be applied only to intact skin surfaces and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or with mucous membranes.

4.5 Interactions with other medicinal products and other forms of interactions:
Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely. There are no known interactions with Rheumac Gel but for a list of interactions known with oral diclofenac the data sheet for oral dosage forms should be consulted.
Additional information on special populations: Not Applicable
Paediatric population: Not Applicable

4.6 Fertility, pregnancy and lactation:
Pregnancy
The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and
gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:
- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- Renal dysfunction, which may progress to renal failure with oligo-hydroamniosis; the mother and the neonate, at the end of pregnancy, to:
- Possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- Inhibition of uterine contractions resulting in delayed or prolonged labour. Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Rheumac Gel no effects on the suckling child are anticipated.

Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Rheumac Gel should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time.

4.7 Effects on ability to drive and use machines:

Cutaneous application of Rheumac Gel has no influence on the ability to drive and use machines.

4.8 Undesirable effects:

The side-effects which may occasionally occur following Rheumac Gel medication include itching, reddening and outbreak of a skin rash etc. Repeated and prolonged application of Rheumac Gel over relatively large areas of skin may result in systemic side-effects.

4.9 Overdose and Treatment:

Signs and symptoms

The low systemic absorption of Rheumac Gel renders overdoses very unlikely.

However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if Rheumac Gel is inadvertently ingested (1 tube of 100g contains the equivalent of 1000mg of diclofenac sodium). In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory medicines should be used. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from Rheumac Gel overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Anti-inflammatory and Analgesic Gel

ATC code: M02A A15

Rheumac Gel contains Diclofenac which is a non-steroidal anti-inflammatory agent with strong anti- inflammatory and analgesic properties. It exerts its anti-inflammatory Effects by inhibiting cyclo-oxygenase enzyme which is involved in the biosynthesis of prostaglandins. The analgesic effect of Rheumac® 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® 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.

5.2 Pharmacokinetic properties:

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.

5.3 Preclinical safety data:

Not Applicable.

6. Pharmaceutical Particulars:
6.1 List of excipients

- Carbopol 934
- Monopropylene Glycol
- Rectified Spirit
- Peg-400
- Glycerine
- Sodium Sulphite
- Perfume Lavender
- Purified Water

6.2 Incompatibilities:
None known

6.3 Shelf life:
36 months

6.4 Special precaution for storage:
Store in a dry place below 30°C.
Protect from light.
Do not freeze.
Maintain airtight closure.
Keep all medicines out of reach of children.

6.5 Nature and contents of container:
Packed in 20g tubes and contained in a unit box with literature insert.

6.6 Special precaution for disposal and other handling:
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing authorization Holder:
Marketing Authorization Holder:
Company Name: Laboratory and Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.
Country : Kenya
Telephone: +254 20 8040306
Telefax : +254 20 8040309
E-Mail : info@laballied.com.

Manufacturing Site Address:
Company Name: Laboratory and Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.
Country : Kenya
Telephone: +254 20 8040306
Telefax : +254 20 S8040309
E-Mail : info@laballied.com

8. Marketing Authorization Number:
Kenya: H95/335

9. Date of first Registration/ Renewal of the Registration:
Registration: 31/06/1995.
Renewal: Retained Annually.

10. Date of revision of the text:
July, 2023.