RHUMANOL CREAMAGEL

Each 100g **Rhumanol Creamagel** contains:
Diclofenac diethylammonium 1.17g
(equivalent to diclofenac sodium 1.00g)

DESCRIPTION
A white opaque cream-like gel

INDICATIONS
Topical symptomatic treatment of the musculoskeletal inflammatory conditions. Muscle sprain and strain, tendinitis and soft tissue injuries. This preparation is recommended for short term treatment of up to two weeks.

RECOMMENDED DOSAGE
Rub into the affected skin area locally three to four times a day. Wash the hands thoroughly after application. Treatment of more than two weeks is not recommended. Do not apply to the ruptured skin area.

After accessing the risk / benefit ration in each individual patient, the lowest effective dose for the shortest possible duration should be used.

ROUTE OF ADMINISTRATION
For topical use only.

CONTRAINDICATIONS
- Patients with or without chronic asthma in whom attacks of asthma, urticarial or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs)
- Hypersensitivity to diclofenac or any of the excipients
- Third trimester of pregnancy
- The use in children and adolescents aged less than 14 years is contraindicated

WARNINGS AND PRECAUTIONS
- The possibility of experiencing systemic adverse event (those associated with the use of systemic forms of diclofenac) from application of **Rhumanol Creamagel** cannot be excluded if the preparation is used at higher dosage/large amounts over large areas of skin and over a prolonged period.
- Concomitant use of systemic NSAIDs should be cautioned since the possibility of an increase in incidence of untoward effects, particularly systemic side effects, cannot be ruled out.
- **Rhumanol Creamagel** contains propylene glycol which may cause mild, localized skin irritation in some people.
- Like other drugs that inhibit prostaglandin synthetase activity, diclofenac and other NSAIDs can precipitate bronchospasm if administrated to patients suffering from or with a previous history of bronchial asthma.
- **Rhumanol Creamagel** should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be allowed to come in contact with the eyes or mucous membranes and should not be ingested.
- Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.
- Severe cutaneous reactions, including Steven-Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with **Rhumanol Creamagel** should be closely monitored for signs of hypersensitivity reactions. Discontinue **Rhumanol Creamagel** immediately if rash occurs.
- Dermatological effects: Occasional- rashes or skin eruption, cases of hair loss, bullous eruption, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and photosensitivity reactions have been reported.
- **Rhumanol Creamagel** can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
- Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported isolated cases.

DRUG INTERACTION
Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely. There are no known interactions with **Rhumanol Creamagel.**

PREGNANCY AND LACTATION
Pregnancy: The systemic concentration of diclofenac is lower after topical administration, compared to oral formulation. 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/foetal development. Studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of prostaglandin synthesis inhibitor in early pregnancy. The risk is believed to increase with dose and duration of therapy. During first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by 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 third trimester, all prostaglandin synthesis inhibitor may expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension).
- renal dysfunction, which may progress to renal failure with oligohydramnios.

The mother and 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 contraction resulting in delayed or prolonged labour. Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Lactation: Like other NSAIDs, diclofenac passes into break milk in small amounts. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from healthcare professional. Under this circumstance, **Rhumanol Creamagel** should not be applied on the breast of nursing mothers, nor elsewhere on large areas of skin or for prolonged period of time.

SIDE EFFECTS

Immune system disorders
Very rare: hypersensitivity (including urticarial), angioneurotic oedema

Infections and infestations
Very rare: Rash pustular

Respiratory, thoracic and mediastinal disorders
Very rare: Asthma

Skin and subcutaneous tissue disorders
Common: Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus
Rare: Dermatitis bullous
Very rare: Photosensitivity reaction
Not known: Desquamation, skin discolouration

SYMPTOMS AND TREATMENT OF OVERDOSE

Sign and symptoms: The low systemic absorption of **Rhumanol Creamagel** renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if **Rhumanol Creamagel** is inadvertently ingested.

Treatment: Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. Support 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 hemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with NSAIDs should be used. The use of activated charcoal should be considered, especially within a short term (within one hour) of ingestion of a toxic dose.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Cutaneous application of **Rhumanol Creamagel** has no influence on the ability to drive and use machines.

PHARMACODYNAMICS

Topical products for joint and muscular pain, anti-inflammatory preparations, non-steroids for topical use. Diclofenac is a potent non-steroidal anti-inflammatory (NSAID) with effective analgesic, anti-inflammatory and antipyretic properties. Diclofenac exerts its therapeutic effect primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2). This medicine is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and pain of traumatic or rheumatic origin, relieves pain and decreases swelling.

PHARMACOKINETICS

When diclofenac sodium is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of diclofenac sodium.

After topical administration of **Rhumanol Cremagel** to hand and knee joints diclofenac can be measured in plasma, synovial tissue, and synovial fluid.

EXCIPIENTS

Liquid paraffin, diethylamine, carbomer 934, cetiol V, perfume RS 1655, isopropyl alcohol, propylene glycol, purified water

PACKING/ PACK SIZE

Aluminium tube of 20g

STORAGE CONDITIONS & USER INSTRUCTIONS

Store in a cool dry place below 30°C.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

Shelf life: Please refer to the outer box label

Manufactured by:

T.O Chemicals (1979) Ltd
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