

# RUFENAL

## Emulgel

### Composition

Each gram contains Diclofenac diethyl ammonium equivalent to 1% Diclofenac sodium.

### Action

Rufenal Emulgel is an anti-inflammatory and analgesic preparation designed for external application. It contains a quantity of active substance equivalent to 1% Diclofenac sodium. The white, creamy, non-greasy preparation can easily be rubbed into the skin.

Experimental studies on animals have shown that, when applied locally, the active substance penetrates the skin, accumulates in the underlying tissue, and combats both acute and chronic inflammatory reactions.

In the presence of inflammation of traumatic or rheumatic origin, the anti-inflammatory and analgesic properties of Rufenal Emulgel elicit a clinical response characterised by a marked decrease in inflammatory swelling. Rufenal Emulgel also affords effective relief from tenderness and pain on movement.

When Rufenal Emulgel is applied locally, the active substance is absorbed through the skin.

Determined by reference to the urinary excretion of Diclofenac and its hydroxylated metabolites, the amount of Diclofenac absorbed following local application of Rufenal Emulgel to the skin in healthy subjects - as compared with oral administration of Rufenal coated tablets - is equivalent to approx. 6% of the dose applied. In patients with rheumatoid arthritis who had received repeated treatment with Rufenal Emulgel the concentrations measure in the region of the inflamed wrist - both in the synovial fluid and in synovial tissue removed during surgery - proved higher than the plasma concentrations. This finding confirms that Diclofenac penetrates into the inflamed zone following local application.

### Indications

For the local treatment of

- Traumatic inflammation of the tendons, ligaments, muscles, and joints, e.g. due to sprains, strains and bruises.
- Localised form soft-tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome and bursitis.
- Localised rheumatic diseases, e.g. osteoarthrosis of peripheral joints and of the vertebral column.

### Contraindications

Hypersensitivity to Diclofenac, acetylsalicylic acid, and other non-steroidal anti-inflammatory drugs, as well as to isopropanol or propylene glycol.

### Adverse Reactions

Diclofenac Emulgel is usually well tolerated. Itching, reddening or smarting of the skin or outbreak of a skin rash may occasionally occur.

Photosensitivity reactions have been observed in isolated cases.

Where Diclofenac Emulgel is applied to relatively large areas of skin and over a prolonged period, the possibility of systemic side effects cannot be completely excluded.

### Precautions

Diclofenac Emulgel 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.

Not to be taken by mouth.

### Pregnancy

Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

### **Dosage and Administration**

Depending on the size of the painful site to be treated, apply 2-4 grams Rufenal Emulgel from 3-4 times daily to the affected parts and rub in gently.

Rufenal Emulgel can also be employed as accompanying treatment together with other dosage forms of Rufenal.

### **Presentation**

Tubes of 30 grams.