

## **DICLOMAX<sup>®</sup> 1% Emulgel**

( Diclofenac diethylamine )

### **PROPERTIES**

Diclomax emulgel is a non-steroidal anti-inflammatory drug with antirheumatic and analgesic properties, intended for topical administration. It is a non-greasy preparation, easy to rub into the skin, and has a soothing and cooling effect at the painful area.

Diclomax emulgel is effective in relieving pain and reducing edema of the affected area.

Diclomax emulgel penetrates rapidly into the affected tissues and the active substance can be detected in plasma, synovial tissue and synovial fluid after topical administration.

### **INDICATIONS**

Diclomax emulgel is indicated for the relief of pain and inflammation in the following cases:

- Post-traumatic inflammation and swelling of the ligaments, tendons, joints, and muscles such as sprains, strains, and bruises.
- Localized conditions of soft-tissue rheumatism such as periarthopathy, tenosynovitis, and bursitis.
- Painful conditions of the vertebral column such as neck pain, and osteoarthritis of the spinal joints.

### **DOSAGE AND ADMINISTRATION**

In general, patient should apply 2-4 g of Diclomax emulgel 3-4 times daily to the affected sites and gently rub in.

Administration is usually depending on the size of the painful area.

The duration of therapy depends on the indication and response of the patient.

Dosage and indications have not yet been established in children using this preparation.

### **CONTRAINDICATIONS**

Hypersensitivity to diclofenac, acetylsalicylic acid, and other non-steroidal anti-inflammatory agents, and to isopropanol or propylene glycol. Patients with or without chronic asthma in whom attacks of asthma urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs.

### **PRECAUTIONS**

Animal studies have shown no risks for the fetus, during the 1st and 2nd trimesters of pregnancy but no controlled studies in pregnant women are available (FDA Pregnancy Category B during 1st and 2nd trimesters). Diclofenac should not be given during the 3rd trimester (FDA Pregnancy Category D during 3rd trimester). No data is available in nursing women using this medicament.

This medicament should be applied only to intact skin, and not to broken skin or open wounds.

Caution should be exercised to avoid any contact of this medicament with the eyes or mucous membranes. The possibility of systemic reactions can not be completely ruled out if this preparation is applied to large areas for prolonged periods.

Concomitant use of oral NSAIDs should be cautioned as the incidence of undesirable effects especially systemic side effects may increase. It should not be co-administered with other products containing Diclofenac.

### **SIDE EFFECTS**

This preparation is generally well tolerated. Side effects are infrequent and mild in nature. These include local reactions : Occasional allergic or non-allergic contact dermatitis (with symptoms and signs such as itching, reddening of the skin, oedema, papules, vesicles, bullae, or scaling).

Systemic reactions: Isolated cases: generalized rash, hypersensitivity reactions (e.g. asthma attack, angioedema); photosensitivity reactions.

### **OVERDOSAGE**

The low systemic absorption of diclofenac when administered topically makes overdose very unlikely. Significant systemic reactions resulting from improper use or accidental overdosage (such as in children) should be managed by taking the necessary supportive measures.

### **PRESENTATION**

Diclomax 1% emulgel: Diclofenac sodium (as Diclofenac diethylamine) 10 mg / 1g.

#### **THIS IS A MEDICAMENT**

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

The doctor and the pharmacist are experts in medicine, its benefits and risks.

Do not by yourself attempt period of treatment prescribed for you.

Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children



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