DIFSOM GEL

(Diclofenac Diethylammonium - 10 mg)

COMPOSITION

Active ingredient: Diclofenac Diethylammonium, stated strength 10 mg. The quantitative basis (per gram or other declaration) and excipients are to be taken from the approved formulation. For topical use.

DESCRIPTION

Difsom Gel contains diclofenac diethylammonium, a non-steroidal anti-inflammatory drug (NSAID) for local application to the skin.

PHARMACOLOGY

Diclofenac inhibits cyclo-oxygenase pathways and prostaglandin synthesis, providing local analgesic and anti-inflammatory action. After application to intact skin, diclofenac reaches underlying inflamed tissue; systemic exposure is much lower than with oral treatment, but is not absent.

INDICATIONS

For local symptomatic relief of pain, tenderness and inflammation associated with sprains, strains, bruises, and localized soft-tissue rheumatic conditions. Some diclofenac gel formulations are used for osteoarthritis of superficial joints under medical advice.

DOSAGE AND ADMINISTRATION

For external cutaneous use. In reference diclofenac diethylammonium 1.16% gels, adults and adolescents aged 14 years and above apply approximately 2-4 g to the affected area 3-4 times daily, rubbing in gently. Exact dosage must correspond to the confirmed strength of Difsom Gel. Use the smallest effective amount for the shortest possible period. Consult a physician if symptoms worsen or persist.

METHOD OF APPLICATION

Apply only to intact skin. Wash hands after use unless hands are being treated. Allow the gel to dry before applying a loose, breathable dressing. Do not use with an airtight occlusive dressing. Avoid bathing immediately after application.

CONTRAINDICATIONS

Hypersensitivity to diclofenac or ingredients of the gel; previous asthma, urticaria, rhinitis or angioedema caused by aspirin or other NSAIDs; third trimester of pregnancy. Standard reference formulations are contraindicated in children below 14 years.

WARNINGS AND PRECAUTIONS

Avoid eyes, mouth, mucous membranes, wounds and broken or diseased skin. Stop use if rash, wheezing, facial swelling or other allergic symptoms occur. Avoid excessive sunlight on treated areas. Application over large areas, in excessive doses or for prolonged periods can increase systemic NSAID adverse effects. Use cautiously in patients with previous gastrointestinal bleeding, heart, renal or liver disorders.

ADDITIONAL PRECAUTIONS

Do not ingest. Check whether the actual formulation contains flammable excipients; if so, avoid smoking and open flames and keep contaminated fabric away from ignition sources. Keep the product away from children.

DRUG INTERACTIONS

Clinically significant interactions are unlikely with recommended topical use because systemic absorption is low. Concomitant oral or topical NSAIDs may increase adverse effects. Inform the physician about medicines including anticoagulants and other anti-inflammatory agents.

PREGNANCY

Do not use in the third trimester. During the first and second trimesters, use only if clearly necessary and prescribed, at the lowest dose for the shortest duration. NSAID exposure may pose fetal risks. Patients planning pregnancy should seek medical advice.

LACTATION

Diclofenac may pass into breast milk in small quantities. Use while breastfeeding only on professional advice. Do not apply to breasts, large skin areas or for extended periods.

PEDIATRIC AND GERIATRIC USE

Reference 1.16% products are not recommended or are contraindicated below 14 years, depending on local labeling. Older adults generally use the adult topical regimen, with consideration of concomitant illness and medication.

ADVERSE REACTIONS

Common local reactions include rash, itching, redness, eczema and contact dermatitis. Rarely, blistering dermatitis may occur. Very rare reactions include photosensitivity, urticaria, angioedema, asthma or other serious hypersensitivity reactions. Discontinue treatment and seek care for severe reactions.

OVERDOSAGE

Excessive topical use is unlikely to produce acute toxicity, but may increase adverse effects. Wipe away excess gel. Accidental ingestion can cause systemic NSAID toxicity; seek urgent medical advice. Management is supportive and symptomatic.

EFFECTS ON DRIVING

Topical diclofenac is not expected to impair the ability to drive or operate machinery.

STORAGE

Keep the container tightly closed and out of reach of children. Protect from excessive heat and follow the temperature limit stated on the approved pack labeling.

PRESENTATION

Difsom Gel: 20 g tube.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.