

DIFSOM

(Diclofenac Sodium)

Sterile Ophthalmic Solution 0.1%

Composition:

Each ml contains:

Diclofenac sodium 1.00 mg.

(Vega Specs.)

Preservative: Thiomersal.

Action:

Diclofenac sodium is a topical, non-steroidal, anti-inflammatory product for ophthalmic use. It is also a potent cyclooxygenase inhibitor with anti-inflammatory, analgesic and antipyretic properties.

Chemically it is 2-[(2, 6-dichlorophenyl) amino] benzene acetic acid, mono sodium salt, with an empirical formula of $C_{14}H_{10}Cl_2NO_2Na$.

Indications:

Inhibition of miosis during cataract surgery. Post-operative inflammation after cataract surgery and other surgical procedures. Chronic conjunctivitis, kerato conjunctivitis, painful post traumatic conditions of the cornea and conjunctiva. Pre-operative and post-operative prevention of cystoids macular edema associated with lens extraction and intra ocular lens implantation. Non-infectious inflammatory conditions affecting the anterior region of the eye (e.g. chronic non-infectious conjunctivitis). Post-traumatic inflammation in penetrating and non penetrating wounds (as an adjuvant to local anti-infective therapy).

Contraindications:

It is contraindicated in patients concurrently wearing soft contact lenses and in patients who are hypersensitive to any component of the medication. Like other non-steroidal anti-inflammatory agents, it is contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis have been precipitated by acetylsalicylic acid or other prostaglandin synthetase inhibitors.

Adverse Effects:

The following unwanted effects have been observed during clinical studies with diclofenac sodium ophthalmic solution.

Occasional: mild to moderate, transient stinging and/or blurred vision directly after application of the drops.

Rare: hypersensitivity reactions in the form of itching, redness and photo phobia.

Precautions:

It is recommended that diclofenac sodium ophthalmic solution drops be used with caution in surgical patients with known bleeding tendencies or who are receiving other medications that may prolong bleeding time.

Patients who wear contact lenses should only use when the lenses are removed. If infection is present or there is a risk of infection, appropriate treatment (e.g. with antibiotics) should be given concomitantly.

Patients whose vision becomes blurred after application should not drive or use machinery.

Pregnancy:

Reproduction toxicity studies carried out in animals have yielded no evidence of risk to the fetus, but no controlled studies have been conducted in pregnant woman.

Since no experience is available to confirm the safety of diclofenac sodium ophthalmic solution during pregnancy and lactation.

It is advisable not to use the preparation unless there are compelling reasons for doing so.

Dosage and Administration

Cataract Surgery

One drop of Difsom Ophthalmic solution should be applied to the affected eye, 4 times daily beginning 24 hours after cataract surgery and continuing throughout the first 2 weeks of the postoperative period.

Corneal Refractive Surgery

One or two drops of Difsom Ophthalmic solution should be applied to the operative eye within the hour prior to corneal refractive surgery. Within 15 minutes after surgery, one or two drops should be applied to the operative eye and continued 4 times daily for up to 3 days.

How Supplied:

5 ml sterile ophthalmic solution in plastic bottle.

Storage and Instructions:

Store below 30°C.

Protect from hat and sunlight.

Keep out of the reach of children.

Use within four weeks after first opening the bottle.

خوراک: ڈاکٹری ہدایات کی مطابق استعمال کریں۔

ہدایات: دوا کو دھوپ اور گرمی سے بچائیں۔

• 30 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

پہلی دفعہ بوتل کھولنے کے بعد دوا کو چار ہفتوں تک استعمال کیا جاسکتا ہے۔



Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.

30 Km, Multan Road, Lahore, Pakistan.