I-GESIC™

1. Composition

Each ml of I-GESIC Eye Drop contains:

Diclofenac sodium	0.1%

2. Dosage form and strength

I-GESIC is available in a 5 ml lupolen vial.

3. Clinical particulars

3.1 Therapeutic indication

I-GESIC is indicated for:

- The treatment of post-operative inflammation in patients who have undergone cataract extraction and IOL implantation.
- Trabeculoplasty and photorefractive keratectomy.
- In ocular inflammatory conditions like iritis, iridocyclitis, chronic conjunctivitis and post-operatively. For the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery.

3.2 Posology and method of administration

As directed by physician.

3.3 Contraindication

Hypersensitivity to diclofenac or other non-steroidal anti-inflammatory drugs (NSAIDs) and while using soft hydrogel contact lenses.

3.4 Special warnings and precautions for use

- I-GESIC, like other NSAIDs, should be used with caution in surgical patients with known bleeding tendencies or who are receiving other medications, which may prolong bleeding time.
- I-GESIC may slow or delay healing.
- Elevations in intra-ocular pressure may occur with I-GESIC following its use in cataract surgery.

3.5 Drug interactions

- There are no major drug interactions with the use of I-GESIC. It can be concurrently used with cycloplegics, mydriatics, beta-blockers, antibacterials and carbonic anhydrase inhibitors.
- I-GESIC should be used with caution along with oral anticoagulants.

3.6 Use in special population

- Paediatric: Safety and effectiveness in paediatric patients have not been established.
- Geriatric: No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.
- Liver impairment: Use with caution.
- Renal failure: Diclofenac pharmacokinetics has been investigated in subjects with renal insufficiency. No differences in the pharmacokinetics of diclofenac have been detected in studies of patients with renal impairment.
- Pregnancy and lactation: Pregnancy Category C. Reproduction studies performed in mice at oral doses up to 5,000 times (20 mg/kg/day) and in rats and rabbits at oral doses up to 2,500 times (10 mg/kg/day) the human topical dose have revealed no evidence of teratogenicity due to Diclofenac Sodium despite the induction of maternal toxicity and fetal toxicity. In rats, maternally toxic doses were associated with dystocia, prolonged gestation, reduced fetal weights and growth, and reduced fetal survival. Diclofenac Sodium has been shown to cross the placental barrier in mice and rats. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

  It is not known whether topical ophthalmic administration of Diclofenac Sodium Ophthalmic could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

3.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to I-GESIC is known.

3.8 Undesirable effects

- Use of I-GESIC may be associated with transient burning and stinging sensation, keratitis and elevated intra-ocular pressure.

- Rarely patients on I-GESIC may experience abdominal pain, chills, fever and headache

3.9 Overdose

There is limited experience of overdose with I-GESIC. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

4. Pharmacological properties

4.1 Mechanism of action

The anti-inflammatory effects of diclofenac are believed to be due to inhibition of both leukocyte migration and the enzyme cylooxygenase (COX-1 and COX-2), leading to the peripheral inhibition of prostaglandin synthesis. As prostaglandins sensitize pain receptors, inhibition of their synthesis is responsible for the analgesic effects of diclofenac. Antipyretic effects may be due to action on the hypothalamus, resulting in peripheral dilation, increased cutaneous blood flow, and subsequent heat dissipation.

4.2 Pharmacodynamic properties

Diclofenac reduces inflammation and by extension reduces nociceptive pain and combats fever.It also increases the risk of developing a gastrointestinal ulcer by inhibiting the production of protective mucus in the stomach.

4.3 Pharmacokinetic properties

Diclofenac is rapidly absorbed when given as an oral solution, sugar-coated tablets, rectal suppository, or by intramuscular injection. It is absorbed more slowly when given as enteric-coated tablets, especially when this dosage form is given with food. Although diclofenac given orally is almost completely absorbed, it is subject to first-pass metabolism so that about 50% of the drug reaches the systemic circulation in the unchanged form. Diclofenac is also absorbed percutaneously.

At therapeutic concentrations it is more than 99% bound to plasma proteins. Diclofenac penetrates synovial fluid where concentrations may persist even when plasma concentrations fall; small amounts are distributed into breast milk. The terminal plasma half-life is about 1 to 2 hours. Diclofenac is metabolised to 4'-hydroxydiclofenac, 5-hydroxydiclofenac, 3'-hydroxydiclofenac and 4',5-dihydroxydiclofenac. It is then excreted in the form of glucuronide and sulfate conjugates, mainly in the urine (about 60%) but also in the bile (about 35%); less than 1% is excreted as unchanged diclofenac.

5. Nonclinical properties

5.1 Animal Toxicology or Pharmacology

Not required.

6. Description

Already mentioned and covered in the above points.

7. Pharmaceutical particulars

7.1 Incompatibilities

There are no known incompatibilities.

7.2 Shelf-life

36 months.

7.3 Storage and handling instructions

Store in cool and dry place.