Alcon Laboratories, Inc's Ilevro

Jeff Prescott, PharmD, RPh, and Nicole Braccio, PharmD Candidate
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Ilevro (nepafenac ophthalmic suspension) is approved to reduce pain and inflammation resulting from cataract surgery.

The FDA approved Alcon Laboratories, Inc's, Ilevro (nepafenac ophthalmic suspension) 0.3% to reduce the pain and inflammation resulting from cataract surgery. The original approval took place in October 2012, but a labeling revision was made in December, and the official drug marketing launched in late January 2013. The lower strength nepafenac 0.1% is also available as branded Nevanac ophthalmic suspension and was approved by the FDA in 2005 for inflammation associated with cataract surgery.

Pharmacology and Pharmacokinetics

Ilevro is a topical non-steroidal anti-inflammatory prodrug that penetrates the cornea and is converted to a potent active metabolite, amfenac, by ocular hydrolases. Surgical trauma that occurs in ophthalmic surgery activates cyclooxygenase (COX) enzymes that yield prostaglandins, or inflammatory mediators. Both compounds are thought to inhibit COX enzymes, which results in inhibition of prostaglandin production. An advantage of Ilevro is its non-polar structure, which allows effective corneal penetration to a greater extent than other NSAIDs. Ilevro's rapid penetration minimizes contact time with the cornea, resulting in less corneal damage and fewer adverse effects. Peak concentration of Ilevro occurs between 30 and 45 minutes. Concentrations of Ilevro many times higher than therapeutic levels were not shown to affect CYP45 metabolism; therefore, drug–drug interactions involving this pathway are unlikely.

Dosage and Administration

Ilevro is only available as a sterile ophthalmic suspension in a 1.7-ml and 4-ml bottle. Patients should shake well before use and instill 1 drop of Ilevro into the affected eye once daily starting 1 day before cataract surgery, on the day of surgery, and up to 2 weeks into the postoperative phase. It is also recommended to instill 1 drop into the affected eye at least 30 to 120 minutes prior to surgery. There are no drug interactions between Ilevro and other ophthalmic agents such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, or mydriatics. However, if more than 1 agent is administered, they should be instilled at least 5 minutes apart to ensure adequate drug delivery.

Clinical Trials

A double-blind randomized controlled trial assessed efficacy between nepafenac 0.3%, nepafenac 0.1% (Nevanac), and a nepafenac vehicle given 1 day prior to surgery, administered on the day of surgery, and continued into the first 2 weeks of the postoperative period. The primary outcome was clinical cure of inflammation at 14 days postoperative, defined as a score of 0, indicating no aqueous flares or aqueous cells were present. Other outcomes included clinical cure at 7 days postoperative and maintenance of clinical cure at 4 separate visits post–treatment cessation. Results concluded that inflammation and pain resolution were similar between Ilevro and Nevanac, but significantly improved between Ilevro and the vehicle alone. A second randomized controlled trial comparing only Ilevro and a vehicle confirmed these results. Ilevro was superior to the vehicle in resolving inflammation and pain at 7 and 14 days post-surgery. The benefit of Ilevro was demonstrated as early as 1 day post-surgery compared with vehicle. The patient was considered successful if they were declared cured and remained cured at subsequent visits. Additional clinical trials are ongoing to determine clinical significance in ocular surgeries other than cataract surgery.

Contraindications, Warnings, and Precautions

Ilevro is only contraindicated in patients with known hypersensitivity to any of its ingredients or other NSAIDs. The most serious adverse effects that may result from Ilevro are delayed healing, increased bleeding time, and keratitis or corneal inflammation. Contact lenses should not be worn while administering Ilevro. Serious

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damage can occur to the eyes if the bottle becomes contaminated, so taking measures to prevent contamination is essential (ie, avoid touching tip of dropper to eye). Ilevro has not been shown to cause teratogenic effects in rat and rabbit models; however, since no well-controlled studies have been performed in women, Ilevro is pregnancy category C but should be avoided in late pregnancy and in nursing women. Safety in pediatric patients aged under 10 years has not been established and there were no observed differences in the elderly population.

Jeff Prescott, PharmD, RPh, is senior vice president of clinical and scientific affairs at Pharmacy Times. *Nicole Braccio is a PharmD candidate at the Ernest Mario School of Pharmacy at Rutgers University*.

Intellisphere, LLC
666 Plainsboro Road
Building 300
Plainsboro, NJ 08536
P: 609-716-7777
F: 609-257-0701