NOVARTIS

Nevanac (nepafenac)

Nepafenac ophthalmic suspension 0.1%

Basic Succinct Statement

CODE: BSS RD 23 MAR 2016; APPRV 10 JUL 2018

This material is only meant for Healthcare Professionals

Nevanac*

Important note: Before prescribing, consult full prescribing information.

Presentation: Alcon's DROP-TAINER™ dispensing system containing 5mL sterile ophthalmic suspension. Each mL of NEVANAC* suspension contains 1 mg of nepafenac.

Indications: Treatment of pain and inflammation associated with cataract surgery. Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.

Dosage and administration: ♦Shake well before use. ♦One drop of NEVANAC* ophthalmic suspension should be applied to the affected eye(s) three-times-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. ♦For the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients, the dose is 1 drop of NEVANAC in the conjunctival sac of the affected eye(s) 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and up to 60 days of the postoperative period as directed by the clinician. An additional drop should be administered 30 to 120 minutes prior to surgery. ♦NEVANAC* ophthalmic suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics.

Contraindications: Hypersensitivity to the active substance, to any of the excipients, or to other nonsteroidal anti-inflammatory drugs (NSAIDs).

Warnings and Precautions: ♦Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of NEVANAC* ophthalmic suspension and should be monitored closely for corneal health. ♦Topical NSAIDs may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. ♦Post-marketing experience with topical NSAIDs suggests that patients with repeat and/or complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases, dry eye or rheumatoid arthritis may be at increased risk for corneal adverse reactions which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Prolonged use of topical NSAIDs may increase patient risk for occurrence and severity of corneal adverse reactions. ♦There have been reports that ophthalmic NSAIDs may cause increased bleeding of ocular tissues (including hyphaemas) in conjunction with ocular surgery. NEVANAC* ophthalmic suspension should be used with caution in patients with known bleeding tendencies or who are receiving other medicinal products which may prolong bleeding time. ♦NEVANAC* ophthalmic suspension contains benzalkonium chloride which may cause eye irritation and is known to discolor soft contact lenses. Patients should be advised not to wear contact lenses during treatment with NEVANAC* ophthalmic suspension. ♦Benzalkonium chloride has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Close monitoring is

required with frequent and/or prolonged use. ♦An acute ocular infection may be masked by the topical use of anti-inflammatory medicines. NSAIDs do not have any antimicrobial properties. In case of ocular infection, their use with anti-infectives should be undertaken with care. ♦There is a potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory agents.

Adverse drug reactions: The following adverse reactions are classified accordingly: **♦Uncommon (≥1/1,000 to <1/100):** keratitis, punctate keratitis, corneal epithelium defect, conjunctivitis allergic, eye pain, foreign body sensation in eyes, eyelid margin crusting **♦Rare (≥1/10,000 to <1/1,000):** dizziness, headache, blurred vision, photophobia, dry eye, blepharitis, eye irritation, eye pruritus, eye discharge, lacrimation increased, hypersensitivity, nausea, dermatitis allergic **♦Post-Marketing Surveillance:** vomiting, blood pressure increased; [*in order of decreasing seriousness:*] corneal perforation, ulcerative keratitis, corneal thinning, corneal opacity, corneal scar, impaired healing (cornea), visual acuity reduced, eye swelling, ocular hyperaemia.