

(SFK),
MD, of the Gordon
Institute, San Diego,
laser provides the sur-
y to select LASIK flap
izable to individual

Bill would ban physicians from accepting gifts

Boston—The Massachusetts Senate, in a unanimous 36-0 vote, passed health-care

Nevanac[®]
(nepafenac ophthalmic suspension) 0.1%

INDICATIONS AND USAGE

Ophthalmic suspension is indicated for the treatment of pain and inflammation associated with ocular surgery.

CONTRAINDICATIONS

Ophthalmic suspension is contraindicated in patients with previously demonstrated hypersensitivity to any ingredients in the formulation or to other NSAIDs.

Caution should be exercised in patients with a history of cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have exhibited sensitivities to these drugs.

Caution should be exercised when using nonsteroidal anti-inflammatory drugs including NEVANAC[®], there exists the potential for increased risk due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in patients with ocular surgery.

WARNINGS

Caution should be exercised when using topical nonsteroidal anti-inflammatory drugs (NSAIDs) including NEVANAC[®], may slow or delay the healing of corneal epithelial defects. Concomitant use of topical NSAIDs and corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and corticosteroids may increase the potential for healing problems.

Caution should be exercised when using topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in corneal epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These effects are more likely to occur in patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including NEVANAC[®] and should be closely monitored for corneal health.

Caution should be exercised when using topical NSAIDs suggests that patients with complicated ocular surgeries, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), glaucoma, or repeat ocular surgeries within a short period of time may be at increased risk for corneal epithelial breakdown which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Caution should be exercised when using topical NSAIDs also suggests that use more than 1 day prior to surgery or use of topical NSAIDs may increase patient risk for occurrence and severity of corneal adverse events. Caution should be exercised when using NEVANAC[®] ophthalmic suspension be used with caution in patients with known hypersensitivity to any ingredients or who are receiving other medications which may prolong bleeding time.

Use in Patients: NEVANAC[®] ophthalmic suspension should not be administered while wearing contact lenses.

Genotoxicity, Mutagenesis, Impairment of Fertility: Nepafenac has not been evaluated in long-term genotoxicity studies. Increased chromosomal aberrations were observed in Chinese hamster ovary cells treated with nepafenac suspension. Nepafenac was not mutagenic in the Ames assay or in the mouse micronucleus assay. Oral doses up to 5,000 mg/kg did not result in an increase in the formation of polychromatic erythrocytes *in vivo* in the mouse micronucleus assay in the bone marrow of mice. Nepafenac did not impair fertility when administered orally to male and female rats at 3 mg/kg (approximately 10 times the plasma exposure to the parent drug, nepafenac, and the active metabolite, amfenac, at the recommended human topical ophthalmic dose).

Teratogenic Effects.

Category C: Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 times the recommended human dose revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. The maternal plasma exposure to nepafenac and amfenac was approximately 260 and 2400 times the recommended human topical ophthalmic dose for rats and 80 and 680 times the recommended human topical ophthalmic dose for rabbits, respectively. In rats, maternally toxic doses ≥ 10 mg/kg were associated with increased postimplantation loss, reduced fetal weights and growth, and reduced fetal survival.

Caution should be exercised when using nepafenac as shown to cross the placental barrier in rats. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, nepafenac should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the ductus arteriosus (closure of the ductus arteriosus), the use of NEVANAC[®] ophthalmic suspension during pregnancy should be avoided.

Adverse Effects: NEVANAC[®] ophthalmic suspension is excreted in the milk of pregnant rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NEVANAC[®] ophthalmic suspension is administered to a nursing woman.

Use in Pediatric Patients: The safety and effectiveness of NEVANAC[®] in pediatric patients below the age of 10 years have not been established.

Elderly Patients: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

In clinical studies, the most frequently reported ocular adverse events following cataract surgery were conjunctival redness, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky eye. These events occurred in approximately 5 to 10% of patients.

Adverse events occurring at an incidence of approximately 1 to 5% included conjunctival edema, conjunctival discharge, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, tearing and vitreous detachment.

Adverse events may be the consequence of the cataract surgical procedure.

Adverse events reported at an incidence of 1 to 4% included headache, hypertension, sinusitis, and sinusitis.

HOW TO USE NEVANAC

NEVANAC[®] ophthalmic suspension should be applied to the affected eye(s) immediately before use. One drop of NEVANAC[®] ophthalmic suspension should be applied to the affected eye(s) daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first postoperative period.

NEVANAC[®] ophthalmic suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and corticosteroids.

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© 2005 Alcon Laboratories, Inc. 2005. 2. Ke T-L, Graff G, Spellman JM, Yanni JM. Nepafenac, a unique prostaglandin synthetase inhibitor with potential utility in the treatment of trauma-induced ocular inflammation. *Invest Ophthalmol Vis Sci* 46:1000-1005. 3. Lane SS, Modi SS, et al. Nepafenac ophthalmic suspension 0.1% before and after surgery for postoperative anterior chamber inflammation. Paper presented at: American Society of Cataract and Refractive Surgery; April 19, 2005; San Francisco, CA. 4. NEVANAC[®] ophthalmic suspension prescribing information.

cost increases and provide the findings to the general public, require the health-care industry to use computerized medical re-

Vidus Ocular, a privately held company developing a shunt (Aquashunt) to treat glaucoma.

To the editor...

Mind over matter

Fixed, growth mindset makes the difference

We enjoyed reading the recent editorial by Peter J. McDonnell, MD, about personal development ("One-trick ponies," *Ophthalmology Times*, May 1, 2008, Page 4).

What particularly struck us was Dr. McDonnell's query: "What's interesting to me is why some people allow themselves to be incredibly successful in some things they do and extremely poor in others. Is it that they are unaware of their weaknesses, thinking only about what they do well and for which people express admiration? Or do they just not care?"

We were reminded immediately of a book we recently read, *Mindset: The New Psychology of Success*, by Carol S. Dweck, PhD. Dr. Dweck is the Lewis and Virginia Eaton Professor of Psychology in the Department of Psychology at Stanford University, Stanford, CA (www-psych.stanford.edu/~dweck/).

The book's thesis is summarized well by *Publisher's Weekly*:

"A fixed mindset is one in which you view your talents and abilities as ... well, fixed. In other words, you are who you are, your intelligence and talents are fixed, and your fate is to go through life avoiding challenge and failure. A growth mindset, on the other hand, is one in which you see yourself as fluid, a work in progress. Your fate is one of growth and opportunity."

The people described by Dr. McDonnell operate under the fixed mindset. They believe that every potential new challenge represents a reflection of their permanent ability. Therefore, to remain successful in their own eyes, they avoid new challenges.

Alternatively, operating with a growth mindset allows a person to view failure as an opportunity for improvement. Failure is not forever; perseverance permits continued improvement in all areas of life.

We believe many ophthalmolo-

gists grew up with and have maintained a fixed mindset. Given their unusual intellectual talent, as young students they performed exceptionally well in school without much effort. When they got high grades and test scores they believed that these successes reflected their natural ability. Having to work at something meant they weren't naturally smart enough, so sliding by without much sweat represented the highest achievement.

However, later in life they probably came up against something at which they weren't so good. Because having to work at it meant they lacked the natural talent to do it (and always would) they simply avoided it and the ignominy of failure that they knew would always accompany it. Whether in the area of social skills, business acumen, recreational or competitive sports, or within the profession of medicine itself, the fixed mindset eliminated any possibility of improvement.

Dr. Dweck has demonstrated in her research that mindset really does make the difference in performance. The ophthalmologist Dr. McDonnell mentions at the end of his editorial said, "So you quickly learn that you better improve in the areas where you're weak."

This quote demonstrates the key to a growth mindset: improvement is possible, and it takes effort. Once you adopt the view that you can get better by working and training, you can see your own strengths and weaknesses exactly as they are. By believing that your strengths and weaknesses are fixed forever, you simply avoid those activities which expose your weaknesses. You remain a one-trick pony.

Mark Packer, MD, FACS
Eugene, OR

Jennifer H. Smith, MD, FACS
Glenview, IL

Letters to the Editor may be submitted to mdlugoss@advanstar.com. Letters may be edited for clarity and length.



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