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Home >>Newsroom >20 To Its Surgical Product Portf Like { 0	13 Archive > Bausch + Lomb olio At The ASCRS Annual M	Launches PROLENSA™ And Sh leeting	owcases Innovative Additions	<u> </u>	
FOR RELEASE 4/17/2013, ' Bausch + Lo Additions to its U.S. Debut for Spec ROCHESTER, NY — Bausc solution) 0.07 percent, its ne additions to its comprehens upcoming Annual American 19-23). Attendees will also te event and booth talks, and s ophthalmic pharmaceutical <b>New Products and Solution</b> Among its wide range of pu- inflammatory drug (NSAID) ' have undergone cataract su 0.09 percent that provides p unique potency of the borm concentration of the active in be available in 1.6ml and 3r The company also will highl new topical corticosteroid fo products. Introduced in Jann following ocular surgery. Th its mucoadhesive technolog loteprednol is delivered in e Bausch + Lomb will offer de appointment, which can be a distribution agreement with ophthalmic microscopes. The company will also show portfolio for refractive, catara specifically to complement f Endothelial Keratoplasty pror purchase at the Bausch + Lu <b>Scientific Symposia</b> Bausch + Lomb is sponsorif • "A New Advancement in th InterContinental Hotel's Gra • "Bot Talks Bausch + Lomb bi supportin event featuring moderator T anovation and practice mar speakers, including Drs. Ro April 20 and company's G will be on hand to engage th <b>CME Events</b> Bausch + Lomb will nost a s innovation and practice mar speakers, including Drs. Ro April 20 and company's G will be on hand to engage th <b>CME Events</b> Bausch + Lomb will nost a s innovation and practice mar speakers, including Drs. Ro April 20 and company's G will be on hand to engage th <b>CME Events</b> Bausch + Lomb will nost a s innovation and practice mar speakers, including Drs. Ro April 20 and company's G will be on hand to engage th <b>CME Events</b> Bausch + Lomb will present acrylic intraocular lens, the f were reported for any subje The schedule for all Bausch Saturday.	Avennesday Wednesday Wednesday Mednesday Modelasday Saurgical Product A New Once-Daily PROLENS Scial Cataract and Refractive Demonstrations of the VIC th Humb, the global eye hea welve approved nonsteroidal a vie line of ophthalmic surgica Society of Cataract and Refractive Demonstrations of the VIC th + Lomb, the global eye hea society of Cataract and Refractive Demonstrations of the VIC th + Lomb, the global eye hea society of Cataract and Refractive Demonstrations of the VIC th + Lomb, the global eye hea society of Cataract and Refractive Demonstrations of the VIC th + Lomb, the global eye hea society of Cataract and Refractive Demonstrations of the VIC th + Lomb the global eye hea society of Cataract and Refractive argeredient, source you Look, The armaceutical and surgical Society of the treatment of postopera rigrery, <i>PROLENSA</i> is an advo overful and rapid resolution fenace molecule and effective argerdient, bromfenac, while r in bottle sizes. ight <i>LOTEMAX</i> (Be (lotepreding mulation in its line of lotepre ary, <i>LOTEMAX</i> Gel also provid very drop, with no shaking to monstrations of its cutting ed scheduled at the Bausch + Lo Leica Microsystems, the Bau vcase the latest additions to it act and vitreo-retinal surgery. emosecond laser procedure ocedure developed by Thoma omb booth (#1926). Ing three scientific symposia in e Ocular Delivery of Lotepred omb booth (#1926). Ing three scientific symposia in e Ocular Delivery of Lotepred on Ballroom. Irgery: What Really Matters?, Ind Ballroom. Irgery: What Really Matters?, Ind Ballroom. Irgery Kinoking Down Inflamma erry Kim, M.D.; and faculty, D event is scheduled to take pi Ations and Posters 23 podium presentations an irst and only IOL approved in ct at any visit in the clinical st + Lomb podium presentations	DLENSA <sup>™</sup> and Showc Portfolio at the ASCF Sa <sup>™</sup> (bromfenac ophthalmic sol Surgical Suites on Display, with TUS <sup>™</sup> Femtosecond Laser Plati alth company, will debut <i>PROLEN</i> inti-inflammatory ophthalmic solut al instruments and therapeutics at ractive Surgery (ASCRS) Symposi cal equipment demonstrations, at um presentations and posters rela- e <b>More You See</b> lutions, Bausch + Lomb will debut nt prescription eye drop, a new or ative inflammation and reduction of anced formulation of <i>Bromday</i> ® (to of inflammation and pain from cat ocular penetration. The advanced maintaining the convenience of or al etabonate ophthalmic gel) 0.5 pr dednol etabonate C-20 ester cortico ted for the treatment of post-opera of formulation is engineered to adh les dose uniformity, ensuring that oresuspend the drug required. ge surgical platform, the <i>VICTUS</i> T omb booth (#1926). And, with the sch + Lomb booth will feature sev ts Bausch + Lomb Storz® industry This will include a specialized se s and a set of instrumentation for as John, M.D., in Chicago, III. The ncluding the following: dnol Etabonate," on Saturday, April 21 ," on Sunday, April 19 from 7:30 – in its booth covering the future of a led by an impressive and diverses (Mark Packer and Jeff Whitman. thety, M.D., and other members of to a nswer questions. tory Barriers to Success in Refrac avaid F. Chang, M.D.; Uday Devga lace on Saturday, April 20 from 5: d e-posters, including several on the U.S. with labeling that states: udy". <sup>1,2</sup> ns and posters is as follows:	Exact super section of the section	News - Related Links          Media Contacts         2014 Archive         2013 Archive         2012 Archive         2012 Archive         2010 Archive         2009 Archive         2009 Archive         2007 Archive	

**DOCKET A L A R M** Find authenticated court documents without watermarks at <u>docketalarm.com</u>. Majmudar P, et al. "Safety of Besifloxacin Ophthalmic Suspension 0.6 percent in Cataract Surgery Patients: Prospective Surveillance Study." [ASCRS Posters P1: Intraocular Surgery (Cataract and Refractive): KIOSKS (Moscone) Saturday, April 20 8 a.m. – 5 p.m. PDT]

Rajpal R, et al. "Resolution of Anterior Chamber Cells and Flare with Loteprednol Etabonate 0.5 percent Gel: New Treatment for Post-Cataract Inflammation and Pain." [ASCRS Posters P1: Intraocular Surgery (Cataract and Refractive): KIOSKS (Moscone) Saturday, April 20 8 a.m. – 5 p.m. PDT]

Stephenson P, et al. "Clarity of Vision with New Hydrophobic Acrylic IOL." [ASCRS Posters P1: Intraocular Surgery: KIOSKS (Moscone) Saturday, April 20, 8 a.m. – 5 p.m. PDT]

Stodulka P, et al. "High-Volume Use of Femtosecond Laser-Assisted Cataract Surgery." [ASCRS Posters P1: Intraocular Surgery: KIOSKS (Moscone) Saturday, April 20, 8 a.m. – 5 p.m. PDT]

Ang RT et al. "Prospective Comparison of 1 Accommodating and 2 Multifocal IOLs: Visual Acuity, Refractive Outcome and Contrast Sensitivity at Year 1." [ASCRS Paper Session 1-C: Intraocular Surgery Presbyopia-Correcting IOLs: Room 121 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]

Chu R, Pepose JS, Qazi MA et al. "Comparison of NEI-RQL-42 and SVI Quality of Life Measures After Bilateral Implantation of 3 FDA-Approved Presbyopia-Correcting IOLs at 6-months." [ASCRS Paper Session 1-C: Intraocular Surgery Presbyopia-Correcting IOLs: Room 121 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]

Dell SJ et al. "Comparison of Free-Floating Capsulotomy - Rate of 2 Femtosecond Laser Systems for Cataract Surgery." [ASCRS Paper Session 1-B: Intraocular Surgery Femtosecond Laser: Room 130 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT]

Stephenson P et al. "Use of Intraoperative Wavefront Aberrometer with New Aspheric Hydrophobic Acrylic IOL." [ASCRS Paper Session 1-D: Intraocular Surgery Power Calculations: Room 123 (Moscone), Saturday, April 20, 1 – 2:30 p.m. PDT] Chee S, Ti S et al. "Early Visual Outcomes of First 100 Cases of Femtosecond Laser-Assisted Cataract Surgery at Ophthalmic Institution in Singapore." [ASCRS Paper Session 1- G: Intraocular Surgery Femtosecond laser: Room 120 (Moscone), Saturday, April 20, 3 – 4:45 p.m. PDT]

Daya SM, Nanavaty MA, Espinosa M et al. "Ultrasound Power, Translenticular Hydrodissection and Lens Fragmentation in Femtosecond laser Cataract Surgery." [ASCRS Paper Session 1-G: Intraocular Surgery Femtosecond laser: Room 120 (Moscone), Saturday, April 20, 3 – 4:45 p.m. PDT]

Pepose JS, Qazi MA et al. "Prospective Randomized Evaluation of Bilateral Implantation of 3 FDA-Approved Presbyopia-Correcting IOLs at 6-months." [ASCRS Paper Session 1-I: Intraocular Surgery Presbyopia-Correcting IOLs: Room 130 (Moscone), Saturday, April 20, 3–4:30 p.m. PDT]

Qazi MA, Chu R, Pepose JS et al. "Evaluation of Visual Metrics Using OQAS After Bilateral Implantation of Accommodating or Multifocal IOLs." [ASCRS Paper Session 1-I: Intraocular Surgery Presbyopia-Correcting IOLs: Room 130 (Moscone), Saturday, April 20, 3 – 4:30 p.m. PDT]

# Sunday:

Kandavel R, Colvard M et al. "Seven-Year Visual Acuity Outcomes with an Accommodating IOL." [ASCRS Paper Session 2-C: Intraocular Surgery Presbyopia-Correcting IOLs: Room 123 (Moscone), Sunday, April 21, 8– 9:30 a.m. PDT] Page TP et al. "Management of Post-occlusion Surge with Advanced Fluidics." [ASCRS Paper Session 2-E: Intraocular Surgery Phaco Technology: Room 125 (Moscone), Sunday, April 21, 8– 9:30 a.m. PDT]

Schechter B et al. "Improved Surgical Efficiency with Newer Model Phacoemulsification System." [ASCRS Paper Session 2-E: Intraocular Surgery Phaco Technology: Room 125 (Moscone), Sunday, April 21, 8 – 9:30 a.m. PDT]

Roberts, C, Stodulka. P. "Improved Surgical Productivity With Incorporation of Femtosecond Laser in Cataract Surgery." [ASCRS Paper Session 2-A: Intraocular Surgery Femtosecond Laser: Room 120 (Moscone) 8 - 9:30 a.m. PDT]

Whitman J et al. "Anterior Capsulotomy Diameter Accuracy and Refractive Outcomes using Femtosecond Laser." [ASCRS Paper Session 2-A: Intraocular Surgery Femtosecond Laser: Room 120 (Moscone), Sunday, April 21, 8–9:30 a.m. PDT] Haq F, Whitman J et al. "Corneal Flap Creation with New Femtosecond Laser used During LASIK." [ASCRS Paper Session 2-J: Intraocular Surgery Keratorefractive LASIK: Room 123 (Moscone), Sunday, April 21, 1–2:30 p.m. PDT]

Wallace R et al. "Burst Hemiflip Approach to Phacoemulsification: Effect of Stable Chamber Fluidics on Nuclear

Disassembly and Removal." [ASCRS Paper Session 2-O: Intraocular Surgery Phaco: Room 121 (Moscone), Sunday, April 21, 3–4:30 p.m. PDT]

Monday:

Guedj M, Monnet D et al. "Prospective Evaluation of New Hydrophobic Toric IOL." [ASCRS Paper Session 4-C: Intraocular Surgery Toric IOLs: Room 125 (Moscone), Monday, April 22, 8 – 9:30 a.m. PDT]

Malyugin BE, Golovin AV et al. "Clinical Outcomes with New Hydrophobic Acrylic IOL." [ASCRS Paper Session 4-F: Russian Papers: Room 125 (Moscone), Monday, April 22, 8– 9:45 a.m. PDT]

Nichamin LD et al. "Rotational Stability of New Foldable One-Piece Hydrophobic Acrylic IOL." [ASCRS Paper Session 4-B: Intraocular Surgery Monofocal IOLs: Room 121 (Moscone), Monday, April 22, 8 – 9:30 a.m. PDT]

Packer M et al. "Implantation of Glistening-Free One-Piece Hydrophobic Acrylic IOL in Cataract patients: Safety and Visual Outcomes." [ASCRS Paper Session 4-H: Intraocular Surgery Monofocal IOLs: Room 123 (Moscone), Monday, April 22, 10 – 11:30 a.m. PDT]

## About PROLENSA

PROLENSA<sup>™</sup> (bromfenac ophthalmic solution) 0.07 percent is a once-daily, topical nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. PROLENSA is an advanced formulation of BROMDAY® (bromfenac ophthalmic solution) 0.09 percent that provides proven once-daily efficacy with a lower concentration of bromfenac.

# Dosage and Administration

Instill one drop into the affected eye once daily beginning one day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Important Risk Information about PROLENSA (bromfenac ophthalmic solution) 0.07 percent.

# Warnings and Precautions

Sulfite allergic reactions

Slow or delayed healing

Potential for cross-sensitivity

Increased bleeding of ocular tissues

Corneal effects, including keratitis

Contact lens wear

## Adverse Reactions

The most commonly reported adverse reactions in three – eight percent of patients were, anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

Please see full prescribing information(53.5 KB, PDF) for PROLENSA.

### About LOTEMAX GEL

LOTEMAX® GEL is a corticosteroid indicated for the treatment of postoperative inflammation and pain following ocular

agent by the FDA in 1998 as *LOTEMAX* (lotepredenol etabonate ophthalmic suspension) 0.5 percent, indicated for the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, initis, cyclitis, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation. *LOTEMAX* Ointment (loteprednol etabonate ophthalmic ointment) 0.5 percent is also available for the treatment of post-operative inflammation and pain following ocular surgery.

# Dosage and Administration

Invert closed bottle and shake once to fill tip before instilling drops. Apply one or two drops of *LOTEMAX* GEL into the affected eye(s) four times daily after surgery and continuing throughout the first two weeks of the post-operative period. **Dosage Forms and Strengths** 

Topical ophthalmic gel: loteprednol etabonate ophthalmic gel 0.5 percent.

Important Risk Information about LOTEMAX GEL

# Contraindications:

LOTEMAX GEL is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

### Warnings and Precautions

Intraocular pressure (IOP) increase - Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.

Cataracts - Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed healing - Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation and occurrence of perforations in those with diseases causing corneal and scleral thinning. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification.

Bacterial infections - Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infection. In acute purulent conditions, steroids may mask infection or enhance existing infections.

Viral infections – Use of corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal infections - Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

Contact lens wear - Patients should not wear contact lenses when using LOTEMAX GEL.

## **Adverse Reactions**

The most common ocular adverse drug reactions were anterior chamber inflammation (five percent), eye pain (two percent) and foreign body sensation (two percent).

# Please see full prescribing information(155.2 KB, PDF) for LOTEMAX Gel.

# About BESIVANCE

*Besivance*® (besifloxacin ophthalmic suspension) 0.6 percent, is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: Aerococcus viridans\*, CDC coryneform group G, Corynebacterium pseudodiphtheriticum\*, Corynebacterium striatum\*, Haemophilus influenzae, Moraxella catarrhalis\*, Moraxella lacunata\*, Pseudomonas aeruginosa\*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus hominis\*, Staphylococcus lugdunensis\*, Staphylococcus warneri\*, Streptococcus mitis group, Streptococcus oralis, Streptococcus pneumoniae, Streptococcus salivarius\* \*Efficacy for this organism was studied in fewer than 10 infections.

### Dosage and Administration

Instill one drop in the affected eye(s) three times a day, four to twelve hours apart for seven days. (2)

## **Dosage Forms and Strengths**

 $7.5\ \text{mL}$  size bottle filled with five mL of besifloxacin ophthalmic suspension, 0.6 percent (3)

# Important Risk Information about BESIVANCE Contraindications:

None

# Warnings and Precautions

Topical Ophthalmic Use Only.

Growth of resistant organisms with prolonged use.

Avoidance of contact lenses. Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with *Besivance* (besifloxacin ophthalmic suspension) 0.6 percent.

#### Adverse Reactions

The most common adverse reaction reported in two percent of patients treated with Besivance was conjunctival redness.

Please see full prescribing information(214.8 KB, PDF) for Besivance.

## About Bausch + Lomb

Bausch + Lomb is a leading global eye health company that is solely focused on protecting, enhancing, and restoring people's eyesight. Our core businesses include ophthalmic pharmaceuticals, contact lenses and lens care products, and ophthalmic surgical devices and instruments. We globally develop, manufacture and market one of the most comprehensive product portfolios in our industry, which are available in more than 100 countries. Founded in 1853, our company is headquartered in Rochester, NY, and employs more than 11,000 people worldwide.

## REFERENCES

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