PITTSBURGH PRIMARY EYE CARE CONFERENCE





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WELCOME



Dear Colleague,

Welcome to Optometric Education Consultants (OEC) Live Conference Series. If this is your first OEC event, we thank you for joining us. For the many who have previously joined us in-person or streaming, we welcome you back and thank you for your continued support. The philosophy of The Optometric Education Consultants (OEC) is to help optometrists enhance care of their patients through timely, clinically pertinent, and highly interactive education. OEC assembles top clinical educators to deliver high-quality COPE-approved continuing education in a relaxed, comfortable setting. We could not offer the pricing, meals and guest speakers without our exhibitors and ask you to take some time to visit with them during breaks. Play the Industry Partner Game for a chance at receiving either a 50%, 25%, or full refund on your current registration.

Florida licensed doctors wanting transcript quality (TQ) education credit, we will provide a link to the exams to all attendees 1-2 days after the conference. The cost of the exams is \$10 per course and certificates are issued immediately upon taking the online test. CE Broker will be updated a few days later. If you do not need the exams of course simply delete the link. We offer continuing education by examination (CEE) for Illinois licensure. If you do not hold a license in a state requiring examination, then no test is needed to obtain your credits. We also submit to CE Broker for Texas and South Carolina approval as well.

Schedules are developed with your comfort in mind. You have time to learn, interact with exhibitors and, very importantly, relax and enjoy yourself. Regardless of the location, our conferences are always COPE accredited and Florida approved. If you need additional hours and your state allows, consider our national Webinar Series. We have also added enduring courses that can be taken at your leisure. Our enduring and webinar courses are all COPE approved but we ask that you confirm that this type of education is acceptable for your state requirements.

Rosenberg & OEC Abroad, May 22-24

OEC Northern Escape, August 23-25

Barcelona, Spain

Ouebec, Canada

To view upcoming webinars bookmark: webinars To view enduring courses bookmark: enduring

To view upcoming in-person conferences details: Live Conferences

Primary Eye Care Conference, February 17-19 Pittsburgh, PA

CE Sarasota, March 9-10

Sarasota, FL

Sunshine State Summer Conference, June 7-9

Orlando, FL

Music City Fall Classic, September 27-29 Nashville, TN

Again thank-you for trusting OEC with your education needs and enjoy the island!

Greg, Joe, Vanessa, Maureen & Helen

INDUSTRY PARTNERS



Diamond Partmers

BAUSCH+LOMB



Gold Industry Partners





Silver Industry Partners



















SCHEDULE



| | Saturday, February 17, 2024 | 0 |
|-----------------------------------|--|--------------------|
| 7:15 am - 8:00 am | Registration and Breakfast | CE Credit |
| 8:00 am - 8:30 am | Innovation & Information Industry Partner Product Theater - Alcon | No CE credit |
| 8:30 am – 10:10 am | The ABCs of Thyroid Eye Disease – Antibodies, Biologics, and Clinical Pearls Greg Caldwell, OD | 2 hours CEE/TQ |
| 10:10 am -10:40 am | Introductions and Break with Sponsors | |
| 10:40 am – 12:20 pm | Herpes A to Z for the Eye Care Provider Greg Caldwell, OD | 2 hours CEE/TQ |
| 12:20 pm - 1:40 pm | Break with Sponsors & Lunch Talk with Bausch + Lomb | |
| 1:40 pm – 3:20 pm | The Spectrum of Angle Closure Glaucoma Joseph Sowka, OD | 2 hours CEE/TQ |
| 3:20 pm - 3:50 pm | Introductions and Break with Sponsors | |
| 3:50 pm – 5:35 pm | Integrative and Functional Medicine: New Opportunities for Optometry Greg Caldwell, OD | 2 hours CEE/TQ |
| | Sunday, February 18, 2024 | No. of Contrast |
| 7:15 am - 8:00 am | Registration and Breakfast | CE Credit Hours |
| 8:00 am - 8:30 am | Innovation and Information Industry Partner Talk with Weave | No CE credit |
| 8:30 am – 10:10 am | Trending Topics in Neuro-Ophthalmic Disease Patricia Modica, OD | 2 hours CEE/TQ |
| 10:10 am -10:40 am | Break with Sponsors | |
| 10:40 am - 12:20 pm Concurrent | Phone a Friend: The Greatest Cases That I Never Saw Joseph Sowka, OD | 2 hours CEE/TQ |
| 10:40 am - 12:20 pm Concurrent | Common Injections for Optometric Eye Care Marty Carpenter, OD | 2 hours |
| 12:20 pm - 1:40 pm | Break with Sponsors & Lunch Talk with Dompe' | |
| 1:40 pm – 3:20 pm | Optometric Role in the Diagnosis and Management of Headaches Patricia Modica, OD | 2 hours CEE/TQ |
| 3:20 pm - 3:50 pm | Break with Sponsors | |
| 3:50 pm – 5:30 pm | Misdiagnosis and Malfeasance: Fact or Fiction? Joseph Sowka, OD | 2 hours CEE/TQ |

^{*}Note that Educational Sessions and Promotional Sessions will not be held in the same space. This alleviates the 30-minute buffer requirement between sessions.



COURSE NOTES



DOWNLOAD The ABC's of Thyroid Eye Disease - Antibodies, Biologics,

and Clinical Pearls

Greg Caldwell, OD, FAAO

DOWNLOAD Herpes A to Z for the Eye Care Provider

Greg Caldwell, OD, FAAO

DOWNLOAD The Spectrum of Angle Closure Glaucoma

Joseph Sowka, OD

DOWNLOAD Integrative and Functional Medicine: New Opportunities for

Optometry

Greg Caldwell, OD

DOWNLOAD Trending Topics in Neuro-Ophthalmic Disease

Patricia Modica, OD

DOWNLOAD Phone a Friend: The Greatest Cases That I Never Saw

Joseph Sowka, OD, FAAO, Diplomate

DOWNLOAD Common Injection for Optometric Eye Care

Marty Carpenter, OD

DOWNLOAD Optometric Role in the Diagnosis and Management of Headaches

Patricia Modica, OD

DOWNLOAD Misdiagnosis and Malfeasance: Fact or Fiction?

Joseph Sowka, OD

SPEAKERS





Greg Caldwell, OD, FAAO

Greg Caldwell, OD, is a 1995 graduate of the Pennsylvania College of Optometry. He completed a one-year residency in primary care and ocular disease at The Eye nstitute in Philadelphia Pennsylvania. He is a fellow of the American Academy of Optometry (AAO) and a Diplomate of the American Board of Optometry (ABO).

He currently works in Duncansville and Johnstown, Pennsylvania as an ocular disease consultant. Dr. Caldwell's primary focus is the diagnosis and management of anterior and posterior segment ocular disease and he has been a participant in multiple FDA investigations. Dr. Caldwell has lectured extensively throughout the county and over twelve countries internationally. In 2010 he served as President of the Pennsylvania Optometric Association (POA) and served on the AOA Board of Trustees 2013-2016. He is President of the Blair/Clearfield Association for the Blind.



Martin Carpenter, OD

Dr. Martin Carpenter graduated from West Virginia University in 1999 and Southern College of Optometry in 2003. He is co-owner of Fairmont Eye Care, Inc. in Fairmont, WV. He is a member of the West Virginia Association of Optometric Physicians and the American Optometric Association. He is a past president of the WVAOP and was awarded the young OD of the year and OD of the year award from the WVAOP. In 2019 he was awarded the Dr. W. David Sullins, Jr. InfantSee Award. He enjoys practicing full scope medical optometry and advocating for expanded scope of practice.

SPEAKERS





Patricia Modica, OD, FAAO

Dr. Modica is a graduate of the Pennsylvania College of Optometry where she also completed a Residency in Primary Care, followed by a two year Fellowship in Neuro-Ophthalmic Disease. She is currently a Clinical Professor at The State University of New York College of Optometry where she oversees care in the Neuro-Ophthalmic Disease Service and teaches didactic coursework in Neuro-Ophthalmic Disease and Neuroanatomy. She also participates in clinical research involving concussive disorders in adolescents. She has lectured nationally and internationally on topics related to her clinical emphasis in neuro-ophthalmic disorders and has published "Neuro-Ophthalmic System: Clinical Procedures" by Butterworth-Heinemann. She is an active Fellow of the American Academy of Optometry and currently serves as the Chair for the Special Interest Group "Neuro-Ophthalmic Disorders in Optometry".



Joseph Sowka, O.D., FAAO, Diplomate

Dr. Joseph Sowka is an attending optometric physician at Center for Sight in Sarasota, Florida, a large medical-surgical practice where he focuses on glaucoma management and neuro- ophthalmic disease. He was formerly Professor of Optometry at Nova Southeastern University College of Optometry for 28 years where he served as Chief of The Advanced Care Service and Director of the Glaucoma Service at the College's Eye Institute. He was the Program Coordinator and Supervisor for the Ocular Disease Residency. Dr. Sowka is a founding member of both the Optometric Glaucoma Society and Optometric Retina Society. He is also the Founder and Chair of the Neuro-Ophthalmic Disorders in Optometry Special Interest Group for the American Academy of Optometry. Dr. Sowka is a Glaucoma Diplomate of the American Academy of Optometry. He is a partner and co-owner of Optometric Education Consultants.

UPCOMING CONFERENCES





<u>CE Sarasota</u> <u>March 9-10, 2024</u>

The Westin Sarasota

100 Marina View Drive

Sarasota, FL 34236



Barcelona, Spain May 22-24, 2024

H10 Urquinaona Plaza
Plaça Urquinaona,
2 – 08010 Barcelona
Barcelona, Spain

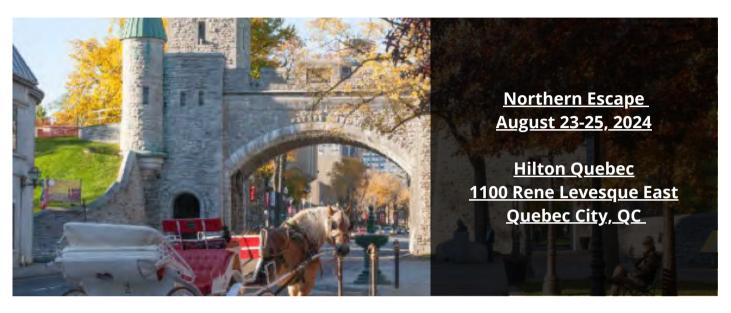


Summer Conference
June 7-9, 2024

<u>Disney's Contemporary Resort</u> <u>4600 World Dr</u> <u>Lake Buena Vista, FL</u>

UPCOMING CONFERENCES











*Pivotal study designs: Two Phase 3, randomized, multicenter, parallel-group studies, APOLLO and LUNAR, evaluating noninferiority of once-daily VYZULTA vs twice-daily timolol maleate 0.5% in patients with open-angle glaucoma or ocular hypertension. Primary endpoint was IOP measured at 9 assessment time points in study eye. APOLLO (VYZULTA, n=284; timolol, n=133) and LUNAR (VYZULTA, n=278; timolol, n=136).²³

INDICATION

VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

- Increased pigmentation of the iris and periorbital tissue (eyelid) can occur. Iris pigmentation is likely to be permanent
- Gradual changes to eyelashes, including increased length, increased thickness, and number of eyelashes, may occur. These changes are usually reversible upon treatment discontinuation
- Use with caution in patients with a history of intraocular inflammation (iritis/uveitis). VYZULTA should generally not be used in patients with active
 intraocular inflammation
- Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. Use with caution in aphakic
 patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema
- There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products that were
 inadvertently contaminated by patients
- Contact lenses should be removed prior to the administration of VYZULTA and may be reinserted 15 minutes after administration
- Most common ocular adverse reactions with incidence ≥2% are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%)

For more information, please see Brief Summary of full Prescribing Information on adjacent page.

References 1. VYZULTA Prescribing Information. Bausch & Lomb Incorporated. 2. Weinreb RN, Scassellati Sforzolini B, Vittitow J, Liebmann J. Latanoprostene bunod 0.024% versus timolol maleate 0.5% in subjects with open-angle glaucoma or ocular hypertension: the APOLLO study. Ophthalmology. 2016;123(5):965-973. 3. Medeiros FA, Martin KR, Peace J, Scassellati Sforzolini B, Vittitow JL, Weinreb RN. Comparison of latanoprostene bunod 0.024% and timolol maleate 0.5% in open-angle glaucoma or ocular hypertension: the LUNAR study. Am J Ophthalmol. 2016;168:250-259.

For the treatment of all stages of neurotrophic keratitis (NK)



NOT JUST ANY SOLUTION

Complete and long-lasting resolution of NK for most patients*

· Up to 72% of patients achieved complete corneal healing in clinical¹⁻³ trials*+ · 80% of these patients remained healed at 1 year (REPARO trial)*4

* Resolution was evaluated in clinical trials as complete corneal healing, defined as the absence of staining in the lesion area and no persistent staining in the rest of the cornea after 8 weeks of treatment and as <0.5-mm lesion staining at 48-week follow-up.1-3

† Key study findings were after 8 weeks of treatment, 6 times daily. REPARO (Study NGF0212): 52 European patients with neurotrophic keratitis (NK) in 1 eye per group; 72% of patients completely healed; vehicle response rate 33.3%. Study NGF0214: 24 US patients with NK in 1 or both eyes per group; 65.2% completely healed; vehicle response rate 16.7%?3



Important Safety InformationLactation

WARNINGS AND PRECAUTIONSThe developmental and health benefits of breastfeeding

Use with Contact Lensshould be considered, along with the mother's clinical

Contact lenses should be removed before applying need for OXERVATE, and any potential adverse effects OXERVATE because the presence of a contact lens on the breastfed infant from OXERVATE.

(either therapeutic or corrective) could theoretically Pediatric Use

limit the distribution of cenegermin-bkbj onto the area The safety and effectiveness of OXERVATE have been of the corneal lesion. Lenses may be reinserted 15 established in the pediatric population. Use of OXERVATE minutes after administration in pediatric patients 2 years of age and older is supported

Eye Discomfortby evidence from adequate and well-controlled trials of

OXERVATE may cause mild to moderate eye discomfort OXERVATE in adults with additional safety data in children. such as eye pain during treatment. The patient should INDICATION

be advised to contact their doctor if a more serious eye OXERVATE® (cenegermin-bkbj) ophthalmic solution reaction occurs.0.002% (20 mcg/mL) is indicated for the treatment

ADVERSE REACTIONS of neurotrophic keratitis.

In clinical trials, the most common adverse reaction was DOSAGE AND ADMINISTRATION eye pain following instillation which was reported in Instill one drop of OXERVATE in the affected eye(s), approximately 16% of patients. Other adverse reactions 6 times a day at 2-hour intervals for eight weeks. occurring in 1% to 10% of OXERVATE patients and more To report ADVERSE REACTIONS, contact Dompé U.S. Inc. frequently than in the vehicle-treated patients included at 1-833-366-7387 or FDA at 1-800-FDA-1088 or corneal deposits, foreign body sensation, ocular www.fda.gov/medwatch.

hyperemia, ocular inflammation and tearing. Please see the Brief Summary of full Prescribing

USE IN SPECIFIC POPULATIONSInformation for OXERVATE on the following page.

Pregnancy**References: 1.** OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. Boston, MA; Dompé U.S. Inc.; 2019. **2.** Bonini S. et al. *Ophthalmology.* 2018;125:1332-1343. There are no data from the use of OXERVATE in pregnant **3.** Pflugfelder SC, et al. *Ophthalmology.* 2020;127:14-26. **4.** Data on File. Clinical Study Report (NGF0212).

women to inform any drug associated risks. Dompé U.S. Inc., 2016.



See more clinical data OXERVATE.com/hcp





Brief Summary of full Prescribing Information

Consult the full Prescribing Information for complete product information, available at www.oxervate.com/prescribing-information.

INDICATIONS AND USAGE

OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% is indicated for the treatment of neurotrophic

DOSAGE AND ADMINISTRATION

General Dosing Information

Contact lenses should be removed before applying OXERVATE and may be reinserted 15 minutes after administration.

If a dose is missed, treatment should be continued as normal, at the next scheduled administration.

If more than one topical ophthalmic product is being used, administer the eye drops at least 15 minutes apart to avoid diluting products. Administer OXERVATE 15 minutes prior to using any eye ointment, gel or other viscous eye drops.

Recommended Dosage and Dose Administration

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

WARNINGS AND PRECAUTIONS

Use with Contact Lens

Contact lenses should be removed before applying OXERVATE because the presence of a contact lens (either therapeutic or corrective) could theoretically limit the distribution of cenegermin-bkbj onto the area of the corneal lesion. Lenses may be reinserted 15 minutes after administration.

Eye Discomfort

OXERVATE may cause mild to moderate eye discomfort such as eye pain during treatment. The patient should be advised to contact their doctor if a more serious eye reaction occurs.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

In two clinical trials of patients with neurotrophic keratitis, a total of 101 patients received cenegermin-bkbj eye drops at 20 mcg/mL at a frequency of 6 times daily in the affected eye(s) for a duration of 8 weeks. The mean age of the population was 61 to 65 years of age (18 to 95). The majority of the treated patients were female (61%). The most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Eye pain may arise as corneal healing occurs.

Other adverse reactions occurring in 1% to 10% of OXERVATE patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, photophobia, tearing, and headache.

Postmarketing Experience

The following adverse reactions have been identified during postapproval use of OXERVATE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Eye disorders: eye irritation, blepharitis (including eyelid margin crusting and eyelid edema) and corneal neovascularization.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.

Lactation

Risk Summary

There are no data on the presence of OXERVATE in human milk, the effects on breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OXERVATE, and any potential adverse effects on the breastfed infant from OXERVATE.

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in this population is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in pediatric patients from 2 years of age and older.

Geriatric Use

Of the total number of subjects in clinical studies of OXERVATE, 43.5 % were 65 years old and over. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis and Mutagenesis

Animal studies have not been conducted to determine the carcinogenic and mutagenic potential of cenegermin-bkbj. Impairment of fertility

Daily subcutaneous administration of cenegermin-bkbj to male and female rats for at least 14 days prior to mating, and at least 18 days post-coitum had no effect on fertility parameters in male or female rats at doses up to 267 mcg/kg/day (1709 times the MRHOD).

In general toxicology studies, subcutaneous and ocular administration of cenegermin-bkbj in females was associated with ovarian findings including persistent estrus, ovarian follicular cysts, atrophy/reduction of corpora lutea, and changes in ovarian weight at doses greater than or equal to 19 mcg/kg/day (119 times the MRHOD).





Alcon's Expanded Pharmaceutical Portfolio

Providing a Range of Treatment Options

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Restore.

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Prokera biologic corneal bandages help empower the eye's healing abilities to expedite a return to normal.





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Meet MiSight 1 day: the only dual purpose contact lens to both **correct vision and control myopia.**§1

Through early intervention, **you have the power** to protect their vision from worsening with the **first and only*** FDA approved† product proven to slow the progression of myopia in children, aged 8-12 at the initiation of treatment.§1 MiSight®, for the love of sight.



SEE MORE



MiSight* 1 day for daily wear



^{*} Only FDA approved soft contact lens designed for myopia control in the U.S.

[†] Indications for Use: MiSight® 1 day (omafilcon A) soft (hydrophilic) contact lenses for daily wear are indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have a refraction of -0.75 to 4.00 diopters (spherical equivalent) with ≤ 0.75 diopters of astigmatism. The lens is to be discarded after each removal.

[§] Compared to a single vision 1 day lens over a 3-year period.

^{1.} Chamberlain P et al. A 3-year Randomized Clinical Trial of MiSight® Lenses for Myopia Control. Optom Vis Sci. 2019;96(8):556-567@2024 CooperVision 15928 01/24

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FILA DIFF























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Train technicians in minutes



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NO CORNEAL CONTACT

Our non-invasive LKC patented sensor strip skin electrodes mean no corneal electrode required



DILATION NOT REQUIRED

Real time pupillography adjusts for pupil size in real time – can be used in patients who are not dilated or in any stage of dilation



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Today's patients are seeking preventative care. Be one of the 1st providers to offer it with the Pharmanex® Biophotonic Scanner, the new standard for carotenoid and macular pigment measurement.



Stop by our table to see how you score, Doc.

Join us on Saturday, August 19th at 1:30pm for a free workshop on how to implement this product and others into your business.



Join us on Saturday, August 19th at 1:30pm for a free workshop on how to implement this technology into your business.

Are your patients getting their eyelash growth serum from you, or someone else who has no knowledge of the eyes, ingredients or potential side effects?

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Help your patients get beautiful, luscious lashes, with results starting



WEEK 12







CEQUA® IS **HOW YU** AND YOOUR **PATIENTS** SEE EYE TO FYE



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CHOOSE THE CLEAR OPTION





might over mites

toeradicate Demodex blepharitis. 1,2

Lotilaner, the active ingredient in XDEMVY^{1,3,4}:



Is a lipophilic agent in an aqueous drop that...



Acts specifi cally via mite GABAgated chloride channels to...



Target, paralyze, and kill Demodex mites

GABA=gamma-aminobutyric acid.

INDICATIONS AND USAGE

XDEMVY (lotilaner ophthalmic solution) 0.25% is indicated for the treatment of Demodex blepharitis.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS

contaminated solutions.

Risk of Contamination: Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fi ngers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using

Use with Contact Lenses: XDEMVY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

Real results





44% and 55% of patients taking XDEMVY in SATURN-1 (N=209) and SATURN-2 (N=193), respectively, achieved a significant improvement in their eyelids (reduction of collarettes to no more than 2 collarettes per upper lid) at Day 43 vs 7% (N=204) and 12% (N=200) of patients taking vehicle (P<0.01 in each trial).1,*

All images are of actual patients who participated in clinical trials for Tarsus Pharmaceuticals.

ADVERSE REACTIONS: The most common adverse reaction with XDEMVY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

Please see next page for a Brief Summary of the full Prescribing Information.

References: 1. XDEMVY [prescribing information]. Tarsus Pharmaceuticals, Inc; 2023. 2. Gao YY et al. Invest Ophthalmol Vis Sci. 2005;46(9):3089-3094. 3. Yeu E et al. Cornea. 2022;42:435-443. 4. Toutain CE et al. Parasit Vectors. 2017;10(1):522.

*The safety and effi cacy of XDEMVY for the treatment of DB were evaluated in a total of 833 patients (415 of whom received XDEMVY) in two 6-week, randomized, multicenter, double-masked, vehicle-controlled studies (SATURN-1 and SATURN-2), Patients were randomized to either XDEMVY or vehicle at a 1:1 ratio, dosed twice daily in each eye for 6 weeks. All patients enrolled were diagnosed with DB. The primary effi cacy endpoint was defi ned as the proportion of patients with collarette reduction to no more than 2 collarettes per upper eyelid at Day 43.

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XDEMVY™ (lotilaner ophthalmic solution) 0.25%, for topical ophthalmic use

BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see the XDEMVY™ package insert for full
Prescribing Information.

INDICATIONS AND USAGE

XDEMVY is indicated for the treatment of *Demodex* blepharitis.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Risk of Contamination Do not allow the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use with Contact Lenses Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

XDEMVY was evaluated in 833 patients with Demodex blepharitis in two randomized, doublemasked, vehicle-controlled studies (Saturn-1 and Saturn-2) with 42 days of treatment. The most common ocular adverse reaction observed in controlled clinical studies with XDEMVY was instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary There are no available data on XDEMVY use in pregnant women to inform any drug associated risk, however, systemic exposure to lotilaner from ocular administration is low. In animal reproduction studies, lotilaner did not produce malformations at clinically relevant doses.

Data Animal Data In an oral embryofetal developmental study in pregnant rats dosed during organogenesis from gestation days 6-19, increased post-implantation loss, reduced fetal pup weight, and incomplete skeletal ossification were observed at 50 mg/kg/day (approximately 1390 times the recommended human ophthalmic dose (RHOD) on a body surface area basis) in the presence of maternal toxicity (i.e., decreased body weight and food consumption). A rare malformation of situs inversus of the thoracic and abdominal viscera occurred in 1 fetus from a pregnant rat receiving 50 mg/kg/day; whether this finding was treatment-related could not be excluded. No maternal or embryofetal toxicity was observed at 18 mg/kg/day (approximately 501 times the RHOD on a body surface area basis). In an oral embryofetal development study in pregnant rabbits dosed during organogenesis from gestation days 7-19, no embryofetal toxicity or teratogenic findings were observed at 20 mg/kg/day (approximately 580-times the RHOD on an AUC basis), even in the presence of maternal toxicity (i.e., decreased food consumption and body weight).

In an oral two-generation reproductive toxicity study, F0 male and female rats were administered lotilaner at doses up to 40 mg/kg/day for 10 weeks before pairing and during the 2-week pairing period (3 weeks for males). Dosing for F0 females continued through lactation day 22. F1 male and female rats were administered lotilaner at 1 and 5 mg/kg/day post-weaning from day 23 for 10 weeks before pairing and during the 2-week pairing period (3 weeks for males). Dosing for F1 parenteral females continued through lactation day 22. There were no clear adverse effects on the F1 generation, and a slightly lower mean body weight during lactation was noted for F2 pups at 5 mg/kg/day. The no observed adverse effect level (NOAEL) was determined to be 5 mg/kg/day (approximately 139 times the RHOD on a body surface area basis).

Lactation: Risk Summary There are no data on the presence of XDEMVY in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lotilaner following 6 weeks of topical ocular administration is low and is >99% plasma protein bound, thus it is not known whether measurable levels of lotilaner would be present in maternal milk following topical ocular administration. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XDEMVY and any potential adverse effects on the breast-fed child from XDEMVY.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 18 years have not been established

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lotilaner.

Mutagenesis Lotilaner was not genotoxic in the

following assays: Ames assay for bacterial gene mutation, in vitro chromosomal aberration assay in cultured human peripheral blood lymphocytes, and in vivo rat micronucleus test.

Impairment of fertility In a two-generation study of reproductive performance in rats, F0 male and female rats were administered lotilaner at oral doses of 40 mg/kg/day for 80 days reduced to 20 mg/kg/day for 47-50 supplementary days. Reduced pregnancy rates and decreased implantation rates were observed in F0 females at doses 20 mg/kg/ day)(approximately 556 times the RHOD on a body surface area basis), which were also associated with maternal toxicity (i.e., decreased body weight and food consumption). No effects on fertility were observed in F0 females at the dose of 5 mg/kg/ day (approximately 139 times the MRHOD on a body surface area basis). No effects on fertility were observed in F0 males at the oral dose of 20 mg/kg/ day (approximately 556 times the RHOD on a body surface area basis), and no effects on fertility were observed in F1 males and females at the oral dose of 5 mg/kg/day (approximately 139 times the RHOD on a body surface area basis).

PATIENT COUNSELING INFORMATION

Handling the Container Instruct patients to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

When to Seek Physician Advice Advise patients

that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of XDEMVY.

Use with Contact Lenses Advise patients that XDEMVY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

Use with Other Ophthalmic Drugs Advise patients that if more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes between applications.

Missed Dose Advise patients that if one dose is missed, treatment should continue with the next dose.

RX only

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