



1

DISCLOSURES

- NONE

2

WHAT DID BACK TO THE FUTURE GET RIGHT...

- Wireless games
- Siri and Google Voice
- Tablets
- 3-D movies
- Zoom
- Flat/Small Cameras
- Flat screen TV's
- Using fingerprints or facial recognition
- Tap to Pay

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OUTLINE

- New medications that were FDA approved in 2020, 2021, and 2022
- What's in the pipeline

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NEW MEDICATIONS THAT LAUNCHED IN 2020

Tepezza

Cystadrops

Upneeq

Durysta

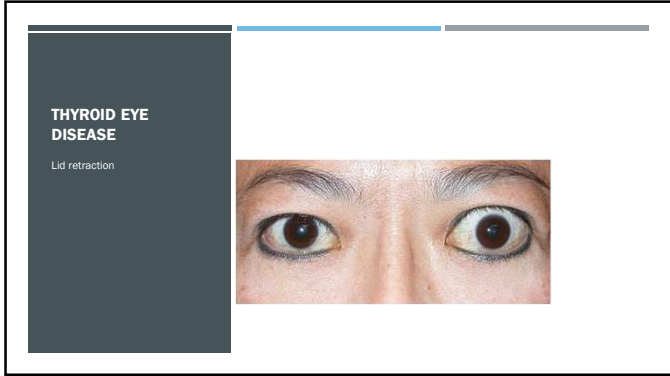
Eysuvis

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THYROID EYE DISEASE

- There is a connection between insulin like growth factor and thyrotropin. IGF-1R overexpresses in an active disease state and combines with thyrotropin and these 2 factors set off the inflammatory cascade.
 - Glycosaminoglycan accumulation → edema, thickened muscles, and proptosis
 - Collagen synthesis → fibrosis, EOM restriction, and lid retraction
 - Proliferation of fatty tissue → increased fat, and proptosis

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TEPEZZA- OPTIC STUDY

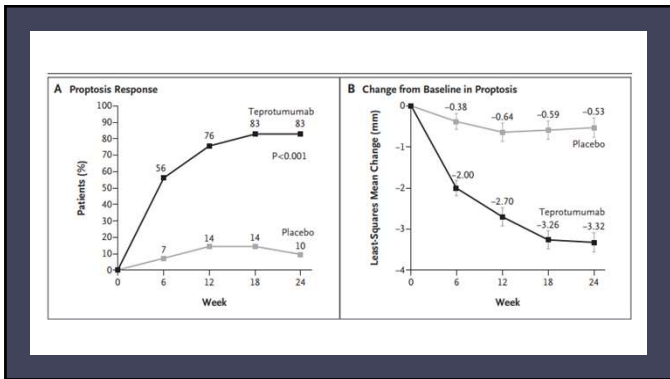
- Teprotumumab is a monoclonal antibody that binds to the IGF-1R the block it signal; it can't then bind to thyrotropin thus preventing inflammatory response.
- Let's look at the study:
 - Conducted in 15 sites

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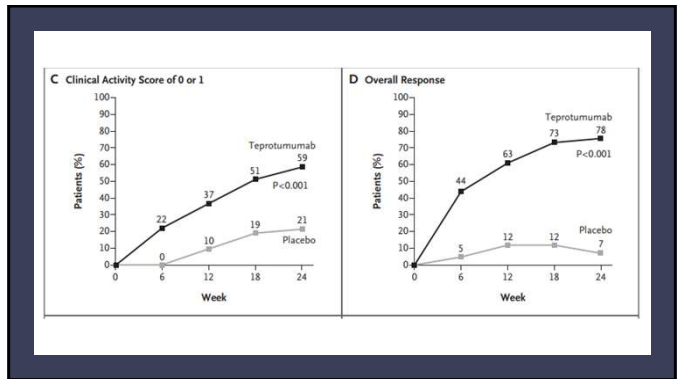
Table 1. Characteristics of the Patients at Baseline*

| Characteristic | Teprotumumab (N=41) | Placebo (N=42) |
|----------------------------------------|---------------------|----------------|
| Sex -- no. (%) | | |
| Male | 12 (29) | 11 (26) |
| Female | 29 (71) | 31 (74) |
| Age -- yr | 51.6±12.6 | 48.5±13.0 |
| Race -- no. (%) | | |
| White | 35 (85) | 37 (88) |
| Black | 4 (10) | 2 (5) |
| Asian | 2 (5) | 1 (2) |
| Other | 0 | 2 (5) |
| Duration of thyroid eye disease -- mo. | 6.2±2.3 | 6.4±2.4 |
| Duration of Graves' disease -- yr | 3.5±6.1 | 2.2±3.2 |
| Smoking status -- no. (%) | | |
| Smoker | 9 (22) | 8 (19) |
| Nonsmoker | 32 (78) | 34 (81) |
| Phylogia measurement -- mm | 22.6±3.32 | 23.26±3.21 |
| Clinical Activity Score† | 5.1±0.9 | 5.3±0.8 |
| Thyroid hormone level -- pmol/liter | | |
| Free triiodothyronine | 5.3±1.8 | 5.3±1.7 |
| Minimum-maximum | 3.3-11.0 | 3.3-11.1 |
| Free thyroxine | 16.5±5.3 | 16.2±4.8 |
| Minimum-maximum | 6.3-34.2 | 8.8-32.2 |
| Thyrotropin level -- mIU/liter | 5.75±1.6 | 4.6±2.17 |
| Minimum-maximum | 0.01-25.77 | 0.01-7.99 |

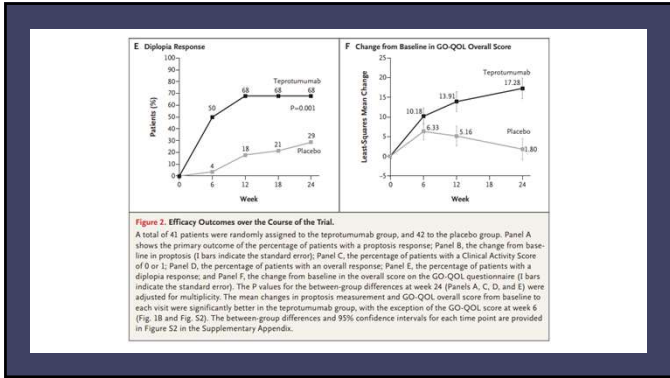
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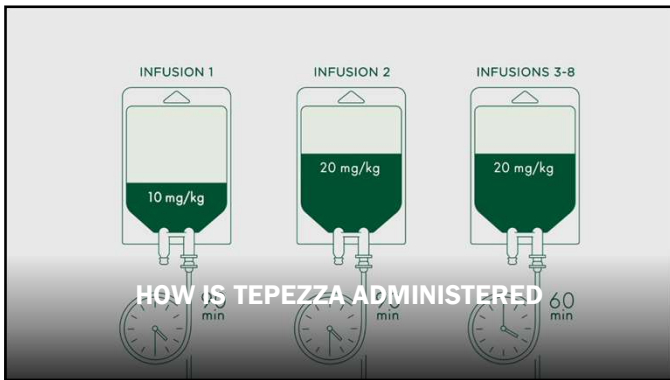


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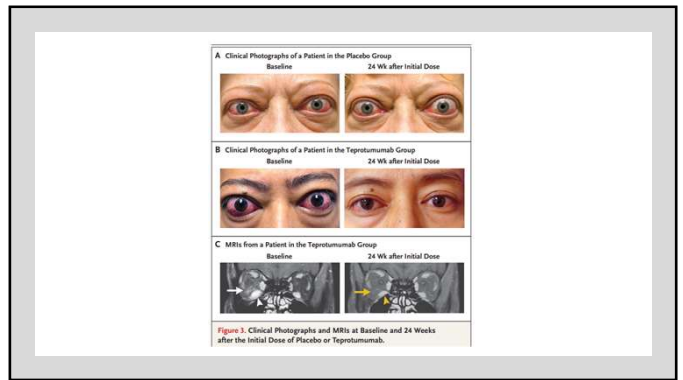
ADVERSE EFFECTS

- Occurred in 5% of patients
- Within 21 days of starting infusions
- Included:
 - Hyperglycemia
 - Headaches
 - Hearing loss

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CYSTINOSIS

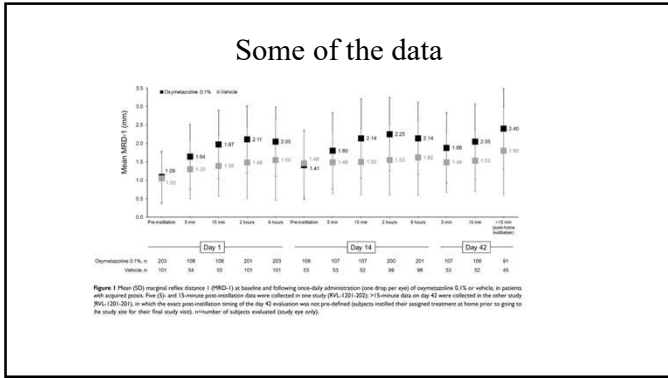
- Rare autosomal recessive condition related to how cystine is stored within a lysosome
- Affecting 1 in 200000 around the world
- Significant systemic and ocular complications

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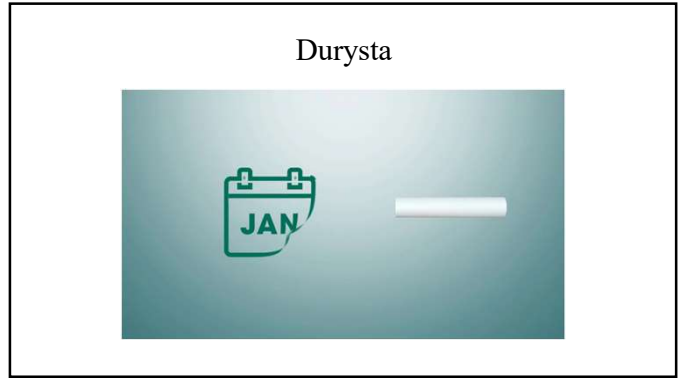
CYSTADROPS

- Cysteamine acts as a cystine-depleting agent by changing the properties of cystine and reduces corneal cystine crystal accumulation
- Use qid, most common dosage during the study

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Let's look at the studies

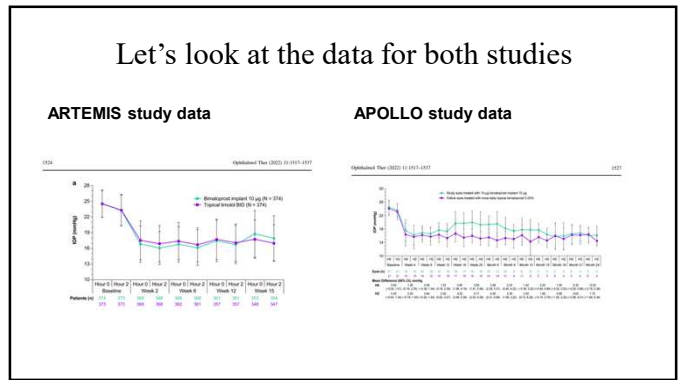
ARTEMIS 1 and 2 study

- Nearly 600 people were enrolled
- Either given bimatoprost 10mcg or 15mcg implant or timolol 0.5% bid
- Implants were placed in on day 1, week 16, and week 32

APOLLO

- 75 people were enrolled
- Bimatoprost implant 6, 10, 15, or 20mcg one eye, bimatoprost 0.3% topical solution fellow eye

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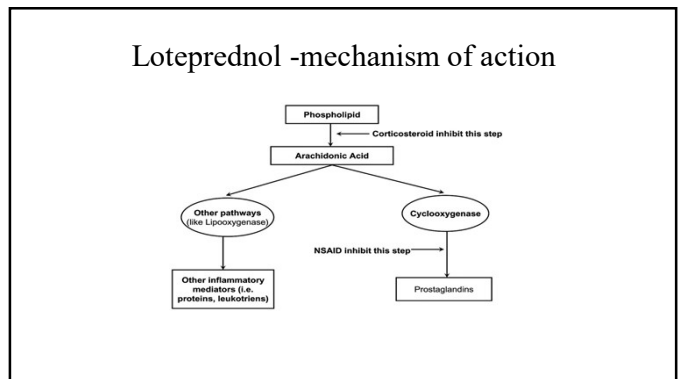


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Treatment for DES

- Low dose loteprednol 0.25% indicated for short term treatment of DES
- Course of treatment is up to 15 days as indicated by the FDA
- Dosage: qid
- Cost: with insurance \$60

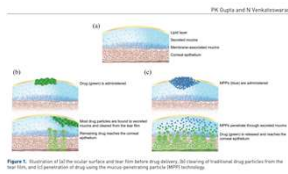
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How it works

- A number of studies: STRIDE 1, 2, and 3
- Use qid for 2 weeks
- Reports indicated that there was a deduction in the symptoms and signs of DES



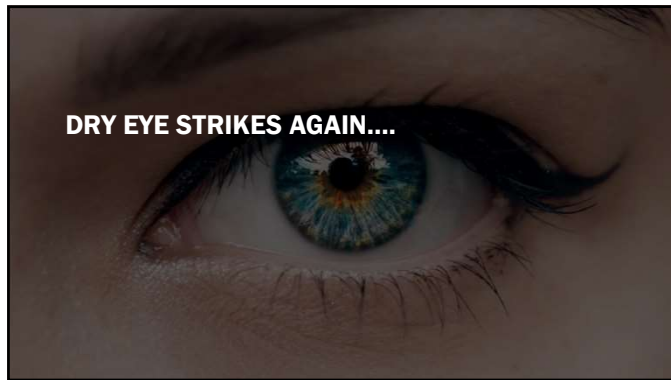
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2021

| | |
|--------|----------|
| Tyvaya | Verkazia |
| Vuity | Susvimo |
| Xipere | |

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DRY EYE STRIKES AGAIN....



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TYRVAYA



- This medication is from the same family that brought us Chantix.
- In fact, the name is varenicline.
- This is in a nasal spray, that stimulates tear production, one spray twice a day!
- There are 2 studies: ONSET and MYSTIC

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MECHANISM OF ACTION - TYRVAYA

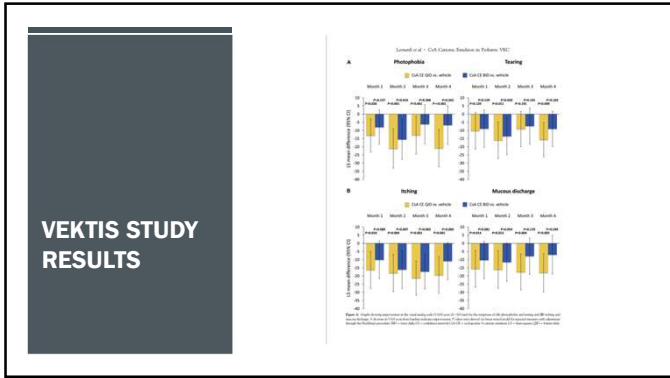
- Aqueous nasal solution which contains the nicotinic acetylcholine receptor agonist, varenicline
- Nicotinic acetylcholine receptors are present within the nasal cavity on the trigeminal nerve
- It is believed that if you stimulate the nicotinic acetylcholine receptors in the nose this will cause activate the lacrimal gland complex, leading to tear production

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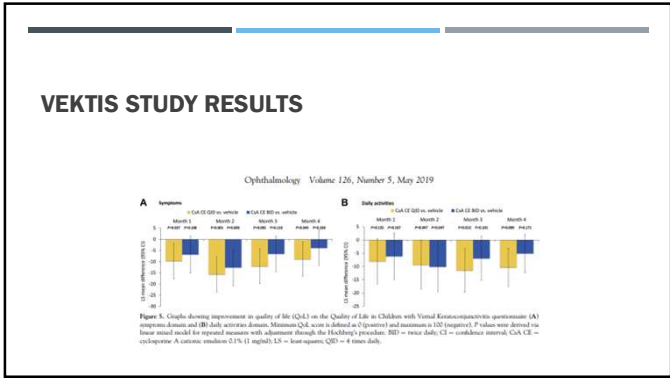
YOU KNOW WHAT'S NEXT.. THE STUDIES

- Patients had to be above age 22, and had an OSDI score of 23 or greater
- History of dry eye symptoms persisting for 6 mos
- Corneal staining
- Schirmer's testing (10mm/5min)
- 758 patients participated in the study

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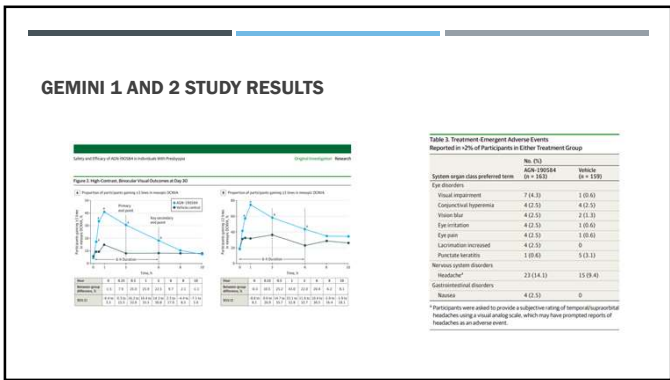
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Retinal Detachments Associated With Topical Pilocarpine Use for Presbyopia

HISHAM AL-HADHRI, HARRY W. FUSNER, AND JUSTIN R. TOWNSEND

• PURPOSE: To present a case series of retinal detachments associated with the use of pilocarpine for presbyopia.

• CASES: Medication case series of 3 cases from 2 patients.

• CASE 1: Patient 1, a 47-year-old man, presented with blurred and double vision. The patient had normal glaucoma 1.25% drops 1 month prior to pilocarpine eye drops. He used the rest of his eye drops 3 days after he started the drops. A dilated examination revealed a subretinal fluid detachment in the superior quadrant with an associated choroidal detachment. The left eye demonstrated a retinal detachment in the superior quadrant with an associated choroidal detachment. He used a small amount of his eye drops to see the patient to include his second visit. A dilated examination revealed a superior retinal detachment from 11 to 12 o'clock with substantial fluid extending into the macula.

• CASE 2: Patient 2, a 60-year-old man, presented 1 week after starting topical pilocarpine 1.25% drops for presbyopia. He used a small amount of his eye drops to see the patient to include his second visit. A dilated examination revealed a superior retinal detachment from 11 to 12 o'clock with substantial fluid extending into the macula.

• CONCLUSIONS: Pilocarpine and other miotics have been associated with retinal detachments and choroidal detachments. There is a potential association for presbyopia, pilocarpine should inform patients of this potential adverse event and consider alternative options of therapy. A screening dilated examination, particularly if there are changes in the degree of blur or an increase in double vision, should be performed. Informed regarding symptoms of retinal tear or detachment, which include flashes, floaters, and visual field loss. (Am J Ophthalmol 2022;153:15-20) © 2022 Elsevier Inc. All rights reserved.

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Case Reports

Ophthalmic Surg Lasers Imaging Retina 2022 Jul;53(7):410-411.
doi: 10.3928/23258160-20220629-01. Epub 2022 Jul 1.

Vitreofoveal Traction Associated With Pilocarpine for Presbyopia

Linus Amarikwa, Suzanne M Michalak, Susan Caul, Prithvi Mruthyunjaya, Ehsan Rahimi

Abstract

Vuity (pilocarpine HCL ophthalmic 1.25%) was approved for the treatment of presbyopia in October 2021. Previous case series have reported the presence of vitreofoveal traction and retinal detachment following pilocarpine administration, but this was not reported in the recent randomized control trials assessing the efficacy of Vuity. The authors report a case of a woman of 65 years who developed vitreomacular traction immediately following the first administration of Vuity, review the literature, and present considerations regarding screening and management of patients starting Vuity. [Ophthalmic Surg Lasers Imaging Retina 2022; 53:410-411.].

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SUSVIMO




Image: Roche/Genentech

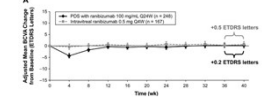
- 1st FDA approved port delivery system for the treatment of exudative AMD.
- Initial insertion of the device with 100mg of Susvimo
- Refilled every 6 months
- Results:

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Optical Density (OD) Values (20, 200, 1,000, 2,000)

Table 1. Ocular and Systemic Concentrations of Active Suspensions

| Observations | Patient System and Port Delivery System (n = 24) | Systemic (n = 24) | OD (n = 24) |
|---------------|--------------------------------------------------|-------------------|-------------|
| Pre-treatment | 0.00 | 0.00 | 0.00 |
| Day 1 | 0.00 | 0.00 | 0.00 |
| Day 2 | 0.00 | 0.00 | 0.00 |
| Day 3 | 0.00 | 0.00 | 0.00 |
| Day 4 | 0.00 | 0.00 | 0.00 |
| Day 5 | 0.00 | 0.00 | 0.00 |
| Day 6 | 0.00 | 0.00 | 0.00 |
| Day 7 | 0.00 | 0.00 | 0.00 |
| Day 8 | 0.00 | 0.00 | 0.00 |
| Day 9 | 0.00 | 0.00 | 0.00 |
| Day 10 | 0.00 | 0.00 | 0.00 |
| Day 11 | 0.00 | 0.00 | 0.00 |
| Day 12 | 0.00 | 0.00 | 0.00 |
| Day 13 | 0.00 | 0.00 | 0.00 |
| Day 14 | 0.00 | 0.00 | 0.00 |
| Day 15 | 0.00 | 0.00 | 0.00 |
| Day 16 | 0.00 | 0.00 | 0.00 |
| Day 17 | 0.00 | 0.00 | 0.00 |
| Day 18 | 0.00 | 0.00 | 0.00 |
| Day 19 | 0.00 | 0.00 | 0.00 |
| Day 20 | 0.00 | 0.00 | 0.00 |
| Day 21 | 0.00 | 0.00 | 0.00 |
| Day 22 | 0.00 | 0.00 | 0.00 |
| Day 23 | 0.00 | 0.00 | 0.00 |
| Day 24 | 0.00 | 0.00 | 0.00 |
| Day 25 | 0.00 | 0.00 | 0.00 |
| Day 26 | 0.00 | 0.00 | 0.00 |
| Day 27 | 0.00 | 0.00 | 0.00 |
| Day 28 | 0.00 | 0.00 | 0.00 |
| Day 29 | 0.00 | 0.00 | 0.00 |
| Day 30 | 0.00 | 0.00 | 0.00 |
| Day 31 | 0.00 | 0.00 | 0.00 |
| Day 32 | 0.00 | 0.00 | 0.00 |
| Day 33 | 0.00 | 0.00 | 0.00 |
| Day 34 | 0.00 | 0.00 | 0.00 |
| Day 35 | 0.00 | 0.00 | 0.00 |
| Day 36 | 0.00 | 0.00 | 0.00 |
| Day 37 | 0.00 | 0.00 | 0.00 |
| Day 38 | 0.00 | 0.00 | 0.00 |
| Day 39 | 0.00 | 0.00 | 0.00 |
| Day 40 | 0.00 | 0.00 | 0.00 |
| Day 41 | 0.00 | 0.00 | 0.00 |
| Day 42 | 0.00 | 0.00 | 0.00 |
| Day 43 | 0.00 | 0.00 | 0.00 |
| Day 44 | 0.00 | 0.00 | 0.00 |
| Day 45 | 0.00 | 0.00 | 0.00 |
| Day 46 | 0.00 | 0.00 | 0.00 |
| Day 47 | 0.00 | 0.00 | 0.00 |
| Day 48 | 0.00 | 0.00 | 0.00 |
| Day 49 | 0.00 | 0.00 | 0.00 |
| Day 50 | 0.00 | 0.00 | 0.00 |
| Day 51 | 0.00 | 0.00 | 0.00 |
| Day 52 | 0.00 | 0.00 | 0.00 |
| Day 53 | 0.00 | 0.00 | 0.00 |
| Day 54 | 0.00 | 0.00 | 0.00 |
| Day 55 | 0.00 | 0.00 | 0.00 |
| Day 56 | 0.00 | 0.00 | 0.00 |
| Day 57 | 0.00 | 0.00 | 0.00 |
| Day 58 | 0.00 | 0.00 | 0.00 |
| Day 59 | 0.00 | 0.00 | 0.00 |
| Day 60 | 0.00 | 0.00 | 0.00 |



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ADDITIONAL INFORMATION ABOUT SUSVIMO

JAMA Ophthalmol. 2022 Jun 16 : e221091. Ophthalmology Retina 2022;:1e16

Patient Preference and Treatment Satisfaction With a Port Delivery System for Ranibizumab vs Intravitreal Injections in Patients With Neovascular Age-Related Macular Degeneration


Management of Key Ocular Adverse Events in Patients Implanted with the Port Delivery System with Ranibizumab

Carl C. Auck, MD, FACS; Chad R. Berman, MD; Socha Mahajan, PharmD, MPhE; Robert T. Cheng, MD; Jon M. Sorenson, MD; Mark B. Stuber, MD; Raymond S. Hwang, MD, FRCPC; Vladimir P. Galambos, MD, MSc; Shantha Crane, MD; Alan H. Fishman; Umar Mahomed, MD, MSc; Jeffrey B. Glick, MD, PhD; David J. Provenzi, MD

What do you suspect the preference was monthly injections vs. Port delivery system??

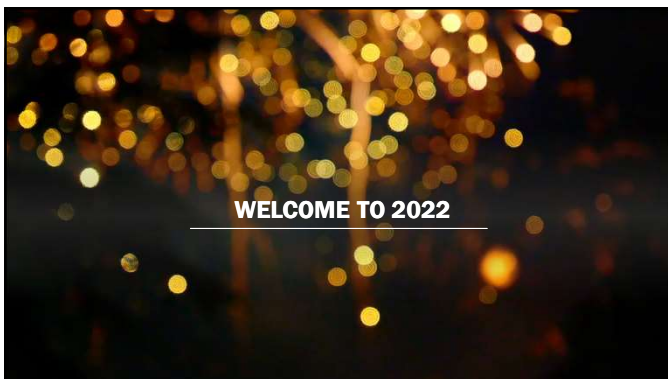
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XIPERE - DOGWOOD AND PEACHTREE TRIALS



XIPERE
(triamcinolone acetonide injectable suspension) 40 mg/mL

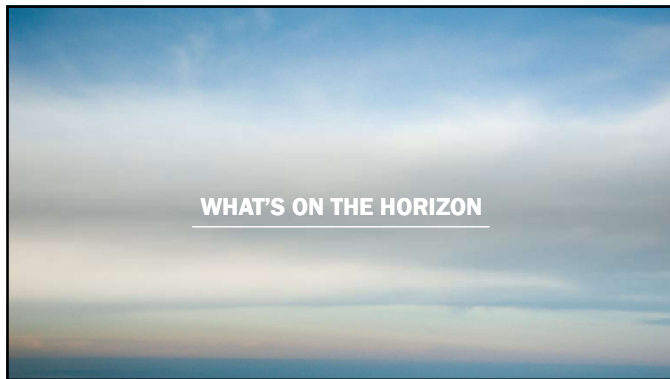
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CIMERLI™
(ranibizumab-eqrn) injection

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ANTERIOR SEGMENT STUFF!

- TP-03
 - Lotilaner 0.25% ophthalmic solution used to treat blepharitis due to demodex.
 - This medication was originally used to treat fleas and ticks in pets
- NOV03 - SEECASE trial
 - Preservative free drop that works to mitigate evaporative dry eye disease
- Selenium sulfide
 - Is a powerful keratolytic agent that can help in the treatment of MGD
 - AZD-MD-001 0.1, 0.5%, and 1% ung dosed bid for up to 3 months
 - Been around in dermatology since 1951
- Reproxalap - RASP inhibitors - anti-inflammatory for use in dry eye, uveitis, and allergic conjunctivitis

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GLAUCOMA

- Angel Study: dual action medication that works on several different prostaglandins
 - Targets Prostaglandins F and E
 - F: what our current medications target uveoscleral tissue to increase aqueous outflow
 - E: targets trabecular meshwork, increasing aqueous outflow
 - Medication is a sepetaprost
- SPECTRUM study:
 - Omidenepeg isopropyl : targets EP2 (type of prostaglandin)
- These target episcleral venous pressure
 - Cromakalim - potassium channel blockers
 - QLS-101: potassium ATP channels

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PNEUMATIC VITREOLYSIS BY INTRAVITREAL GAS INJECTIONS

RETINA. 2020 NOV;40(11):2140-2147, SCI REP. 2021 SEP 10;11(1):18089

Figure 1. VMT preoperative and one month after C3F8 injection. From top to bottom: complete VMT release (A, B); partial VMT release with persistent VMA (C, D); VMT vitreomacular traction; VMA vitreomacular adhesion.

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WOW!! Looks like I am finished!

Thanks for your attention!

PS. I am not answering any questions, LOL!

☺

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