



ASCRS Consensus Statement on VUITY

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Purpose: On August 16, 2022, the Prescribing Information for VUITY (pilocarpine hydrochloride ophthalmic solution) 1.25% was updated following a voluntary submission by Allergan, an AbbVie company, to the U.S. Food and Drug Administration (FDA). New information has now been included in the Warnings and Precautions, Postmarketing Experience, and Patient Counseling Information sections. This ASCRS Task Force was convened to develop an understanding of the data and a preliminary consensus on appropriate counseling of patients regarding risks associated with the use of VUITY.

Overview of the additions to the Prescribing Information for VUITY provided by Allergan

5. Warnings and Precautions has been updated to include warnings regarding:

5.1 Blurred vision from accommodative spasm and dim vision due to miosis.

5.2 Risk of retinal detachment or retinal tears, with an increased risk in patients with a history of retinal pathology.

6.2. Postmarketing Experience (Under 6. Adverse Reactions)

Reported adverse reactions in patients using VUITY postapproval include vitreous detachment, vitreomacular traction, retinal tear, retinal detachment.

17. Patient Counseling Information

Information regarding counseling patients on caution with night driving due to dimming of vision and operating machinery due to blurred vision was added. Patients are advised to seek immediate attention for signs and symptoms of a retinal detachment (i.e., flashes, floaters, or vision loss).

Summary of FDA registration study findings

Pooled data of two multicenter, prospective, randomized, vehicle controlled, double-masked studies (n=375) reported no cases of retinal tear or detachment in the study period of 30 days with daily bilateral QAM instillation of VUITY. The study included patients with best distance correction sphere of -4.00 D to +1.00 D (inclusive) and cylinder $\leq \pm 2.00$ D and excluded patients with a history of retinal pathology. The primary endpoint showed that significantly more VUITY participants gained ≥ 3 lines in mesopic DCNVA, without losing more than 1 line (5 letters) of CDVA at day 30, hour 3 vs. vehicle. Adverse events reported by at least 5% of patients

receiving VUITY included headache (15%), conjunctival hyperemia (5%), and blurred vision (5%).¹

Review of literature regarding Postmarketing Experience with VUITY

1. A case series described two cases of unilateral retinal detachment occurring within 10 days of initiation of pilocarpine 1.25% for the treatment of presbyopia. The patients were pseudophakic men with pre-existing retinal detachment risk factors including high myopia, lattice degeneration, and prior retinal detachment. Both affected eyes were treated with pars plana vitrectomy, gas tamponade, and endo laser and had an uncomplicated postoperative course.²
2. Three eyes of two patients in their 40s were reported to have retinal tears and detachment soon after instillation of pilocarpine 1.25% for presbyopia. One patient reported noting new onset of flashes and floaters 3 days after use of the drop and was found on examination 1 month later to have retinal tears and limited detachments in both eyes. A second patient noted a visual field defect 5 weeks after instillation of the drop and had a retinal detachment with subretinal fluid extending into the macula.³
3. This is a case report of a 65-year-old patient who developed vitreomacular traction following instillation of one dose of pilocarpine 1.25%.⁴

Summary of Task Force recommendations

An increased risk of retinal traction, tears, and detachment has been associated with miotics such as pilocarpine. Physicians should inform patients who desire treatment of presbyopia with miotics including pilocarpine of this potential adverse event. The duration of miotic registration studies and the included population parameters should be considered when applying risk/benefit assessments to specific patients. Before prescribing miotics, one should consider performing a dilated fundus examination as part of the individual risk assessment for retinal detachment. One may also consider other specific diagnostic testing, such as optical coherence tomography (OCT macula), based on clinical considerations. Patients should be educated regarding symptoms of retinal tears or detachment, including flashes, floaters, and visual field loss and should be advised to seek medical attention urgently should any of these symptoms occur.

References

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2. Eton EA, Zhao PY, Johnson MW, Rao RC, Huvard MJ. Rhegmatogenous retinal detachment following initiation of pilocarpine hydrochloride ophthalmic solution 1.25% for treatment of presbyopia. *Retin Cases Brief Rep.* 2022 Aug 12. Online ahead of print.

3. Al-Khersan H, Flynn HW Jr, Townsend JH. Retinal detachments associated with topical pilocarpine use for presbyopia. *Am J Ophthalmol.* 2022;242:52–55.

4. Amarikwa L, Michalak SM, Caul S, Mruthyunjaya P, Rahimy E. Vitreofoveal traction associated with pilocarpine for presbyopia. *Ophthalmic Surg Lasers Imaging Retina.* 2022;53:410–411.

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