NEW DRUG APPROVAL

Brand Name	Vuity™
Generic Name	pilocarpine hydrochloride
Drug Manufacturer	AbbVie Inc.

New Drug Approval

FDA Approval Date: October 28, 2021
Review Designation: Standard
Type of Review: Type 5 - New Formulation or New Manufacturer; New Drug Application (NDA): 214028
Dispensing Restrictions: N/A

Place in Therapy

DISEASE DESCRIPTION & EPIDEMIOLOGY

Presbyopia ("aging sight") is a non-refractive error that also affects visual acuity. Presbyopia occurs when the lens loses its normal accommodating power and can no longer focus on objects viewed at arm's length or closer. As such, it is not considered an ametropic state, but rather one in which the normal physiologic function of lens accommodation has been lost.

Presbyopia usually begins after age 40 when patients start to appreciate the inability to focus on objects at reading distance. In patients with presbyopia, the eye's focusing power for reading is lost progressively and fully by age 65 years.

It is estimated that, in 2015, there were 1.8 billion people with presbyopia worldwide. Approximately 826 million of those had uncorrected or under corrected vision. In the United States, presbyopia is the most common cause of visual impairment due to aging of the "baby boomer" generation, the 76 million Americans born between 1946 and 1964.

Efficacy

The efficacy of Vuity™ for the treatment of presbyopia was demonstrated in two 30-Day Phase 3, randomized, double masked, vehicle-controlled studies, namely GEMINI 1 (NCT03804268) and GEMINI 2 (NCT03857542). A total of 750 participants aged 40 to 55 years old with presbyopia were randomized (375 to Vuity™ group) in two studies and participants were instructed to administer one drop of Vuity™ or vehicle once daily in each eye.

In both studies, the proportion of participants gaining 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA) with the same refractive correction was statistically significantly greater in the Vuity™ group compared to the vehicle group at Day 30, Hour 3.

Table: Primary Efficacy Results from GEMINI 1 and GEMINI 2 Studies (Intent-to-Treat Population)

	GEMINI 1			GEMINI 2		
	VUITY N=163	Vehicle N=160	p-value	VUITY N=212	Vehicle N=215	p-value
Proportion of participants gaining 3-lines or more in mesopic DCNVA, without losing more than 1 line (5 letters) of CDVA at Day 30, Hour 3	31%	8%	p<0.01	26%	11%	p<0.01

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Safety

ADVERSE EVENTS

Most common adverse reactions (>5%) are headache and conjunctival hyperemia.

WARNINGS & PRECAUTIONS

Poor Illumination: Exercise caution in night driving and other hazardous occupations in poor illumination.
Risk of Retinal Detachment: Rare cases of retinal detachment have been reported with other miotics; patients should be advised to seek immediate medical care with sudden onset of vision loss.
Iritis: Caution is advised in patients with iritis.

CONTRAINDICATIONS

Hypersensitivity

Clinical Pharmacology

MECHANISMS OF ACTION

Pilocarpine hydrochloride is a cholinergic muscarinic agonist which activates muscarinic receptors located at smooth muscles such as the iris sphincter muscle and ciliary muscle. Vuity™ contracts the iris sphincter muscle, constricting the pupil to improve near and intermediate visual acuity while maintaining some pupillary response to light. Vuity™ also contracts the ciliary muscle and may shift the eye to a more myopic state.

Dose & Administration

ADULTS

Instill one drop of Vuity™ in each eye once daily.

PEDIATRICS

N/A

GERIATRICS

Refer to adult dosing.

RENAL IMPAIRMENT

No dosage adjustments are needed.

HEPATIC IMPAIRMENT

Regardless of the indication, the initial dosage of oral pilocarpine in patients with moderate hepatic impairment is 5 mg PO twice daily; adjust dosage based on response. Patients with mild hepatic impairment do not require dosage adjustment. Data are lacking in patients with severe hepatic impairment.

Product Availability

DOSAGE FORM(S) & STRENGTH(S)

Ophthalmic solution containing pilocarpine hydrochloride 1.25%.