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Packaging Delivers Micro Dose

March 14, 2021 <u>Hallie Forcinio</u>



Smart packaging opens doors to new products for diagnosis and treatment of eye problems.

Many ophthalmic products for the diagnosis and treatment of eye problems rely on droppers to deliver a dose to the eye. Physics limits the size of the smallest dose to approximately 40 microliters (μ L), an amount that can cause side effects. Dropper delivery also requires the patient's head to be tilted, and the product can become contaminated if the dropper touches the eye or face. Product waste is common because it can be challenging to accurately aim a droplet into the eye, particularly when selfadministering.

To overcome the disadvantages encountered with droppers, Eyenovia has developed the Optejet touchless dispenser, which is capable of repeatably and precisely dispensing micro-doses of $7-9 \mu$ L directly on the cornea from four to five inches away. It works in a horizontal orientation rather than the vertical orientation of the dropper and is easy to operate, reports Michael Rowe, chief operating officer at Eyenovia.

The proprietary Optejet system consists of a base unit and replaceable product cartridge and is protected by multiple patents related to the technology and system. The base unit houses the core of the design, a piezoelectric ejector, plus electronics and battery, and is designed for two or three years of service. A Bluetooth connection allows the Optejet dispenser to be paired with smartphones or tablets and enables dose data to be collected and analyzed in a Cloud-based system so caregivers can monitor usage and adherence. A timeout feature can lock the device until it's time for the next dose. "Future applications may include dosing reminders," reports Rowe.

The replaceable cartridge contains a product-filled

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Packaging Delivers Micro Dose

operation, a unique electric waveform pattern is applied to a piezoceramic disk, which vibrates a plastic membrane with a concentric array of 109 40micron-diameter nozzles. The fluid is ejected from these nozzles in a wave of micro drops, which is called a micro-dose array print. The low-velocity dispersion and a dispensing duration of fewer than 100 milliseconds, quicker than the blink reflex, enhance ease of use. The low-velocity dispersion also makes dose delivery more comfortable. To ensure the dispenser never comes in contact with the face or eye, the nozzle array is recessed and covered by a shutter when not in use (see **Figure 1**). Evenovia plans to add an in-house commercial fill/finish system to its existing sub-assembly manufacturing operation.

The Optejet micro-dose dispenser has been designed for a trio of ophthalmic products under development at Eyenovia. The first product likely to be commercialized is MydCombi, a combination product (tropicamide 1% and phenylephrine 2.5% solution) for mydriasis (pupil dilation) during eye exams. On March 2, 2021, Evenovia announced that FDA accepted its new drug application for MydCombi, and the agency's review is expected in the fourth quarter of 2021. The other two products destined for Optejet dispensing include MicroPine micro-dose atropine to prevent progressive myopia in children, and MicroLine microdose pilocarpine to help improve near vision in adults with presbyopia. The MicroPine product has been licensed to Bausch Health in the United States and Canada. Evenovia also has partnership agreements

Figure 1. CLICK TO ENLARGE. A replaceable product cartridge fits on the reusable Optejet base. A shutter protects the nozzle array. To dispense medication, the patient or caregiver opens the shutter, positions the dispenser at eye level, and presses the button to dispense a micro-dose mist. **Image Property** of Eyenovia, Inc. Used by Permission.

with Senju and Arctic Vision to help commercialize the micro-dose technology. "We are open to additional partnerships that bring the benefits of the technology to other areas in ophthalmology and/or



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the world," says Rowe.

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Hallie Forcinio is Packaging editor for *Pharmaceutical Technology.*

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