

Dextenza® (dexamethasone ophthalmic insert) – New indication

- On October 11, 2021, <u>Ocular Therapeutix announced</u> the FDA approval of <u>Dextenza</u>
 (<u>dexamethasone ophthalmic insert</u>), for the treatment of ocular itching associated with allergic conjunctivitis.
- Dextenza is also approved for the treatment of ocular inflammation and pain following ophthalmic surgery.
- The approval of Dextenza for the new indication was based on three randomized, double-masked, vehicle-controlled efficacy studies in 255 patients with itching associated with allergic conjunctivitis. Patients received Dextenza or its vehicle utilizing a repeat conjunctival allergen challenge mode.
 - In all three trials, Dextenza resulted in lower mean ocular itching scores compared with the vehicle group at all time points throughout the one-month duration of the study. In two of the three studies, a higher proportion of patients had statistically significant reductions in ocular itching on day 8, at 3 minutes, 5 minutes, and 7 minutes post-challenge in the Dextenza group than in the vehicle group.
 - Refer to the Dextenza drug label for complete study results.
- Dextenza is an ophthalmic insert that is inserted in the lower lacrimal punctum into the canaliculus. A single Dextenza insert releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.
 - Dextenza is resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert if necessary. Dextenza is intended for single-use only.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

 $\mbox{RxNews}^{\mbox{\tiny @}}$ is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.