



## 340B Limited Distribution Notice for OXERVATE® (NDC 71981-0020-01)

May 2019

By this Limited Distribution Notice, Dompé U.S., Inc. (“Dompé”) wants to explain how 340B covered entities can access our product OXERVATE®.

OXERVATE® (*cenegermin-bkbj*), a recombinant human nerve growth factor, is an ophthalmic solution indicated for the treatment of neurotrophic keratitis. OXERVATE® was approved by the U.S. Food and Drug Administration pursuant to a Biologics License Application on August 22, 2018. Neurotrophic keratitis is a progressive degenerative disease resulting from a loss of corneal sensation. The disease is characterized by corneal sensitivity reduction, epithelium breakdown, and impairment of corneal healing. The prevalence of neurotrophic keratitis has been estimated to be fewer than five in 10,000 individuals.

OXERVATE® is a highly specialized biological product that is very difficult to manufacture. This difficulty means that production quantity is necessarily limited. In order to ensure that there is adequate supply in the market - including critical safety stock -- Dompé must closely monitor the flow of product through the distribution channel. Limiting the number of distributors and pharmacies with OXERVATE® inventory greatly aids in that effort.

Further, OXERVATE® is particularly sensitive to environmental factors such as temperature. To ensure maintenance of biological activity and to avoid degradation, stringent conditions for storage are necessary. There are currently only two commercial freezers in the United States that have been certified for use in the distribution of OXERVATE®. Dompé’s specialized supply chain calls for strict adherence to thawing protocols and timelines.

Finally, preparation and dosing of OXERVATE® require specialized training and equipment. Dompé trains each dispensing pharmacist on how to handle and administer OXERVATE®, using a custom pipette specifically developed for Dompé.

For these reasons, Dompé makes OXERVATE® available exclusively through its specialty pharmacy partner Accredo Specialty Pharmacy. This limitation applies equally to 340B covered entities and all other commercial dispensaries. OXERVATE® may only be dispensed by Accredo Specialty Pharmacy directly to patients.

Prescriptions for OXERVATE® may be filled through submission via facsimile at 888-454-8488 to Accredo Specialty Pharmacy. The main number for Accredo Specialty Pharmacy is 877-831-8112.

If you have any questions about this distribution limitation, please contact Dompé Customer Service at 833-DOMPE-US (833-366-7387).

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[www.dompe.com](http://www.dompe.com)