



23 January 2023

IMPORTANT PRODUCT INFORMATION

Subject:	New Stability Data Supports Use of STELFONTA[®] (tigilanol tiglate injection) 1 mg/mL Until 42 Months Post-Manufacture
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Dear Doctor,

The purpose of this letter is to inform you that new stability data for STELFONTA[®] (tigilanol tiglate injection) supports use of the product out to 42 months after the date it was manufactured. The extended stability data for STELFONTA in the US is consistent with the advice received from the Food and Drug Administration Center for Veterinary Medicine (FDA/CVM), justified by real-time long term [when stored at 5±3°C (41±5.4°F)] physical, chemical and microbiological stability at 42 months. This change is effective immediately. Examples of the effect from this new supported stability for production batches of STELFONTA are outlined in the table below.

STELFONTA[®] (tigilanol tiglate injection) Lot Number	Currently Labeled Expiry Date	Effect of New Stability Data
B210259	10/2022	04/2024
B220106	09/2024	03/2025

For additional information, contact your local Territory Sales Manager, call our Product Safety and Consulting team (1-800-338-3659, Option 1) or visit: vet-us.virbac.com/stelfonta.

This letter is not intended as a complete description of the benefits and risks related to the use of STELFONTA. Please refer to the enclosed Brief Summary for more information. Always administer the recommended concomitant medications (corticosteroids, H1 and H2 receptor blocking agents) with STELFONTA. Death has occurred following mast cell degranulation when these concomitant medications were not administered appropriately.

Sincerely,

Frank Hurtig, DVM
Director of Pharmacovigilance Consulting & Reporting

Enclosure: STELFONTA Brief Summary

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