

Leucadia Pharmaceuticals Launches Sodium Tetradecyl Sulfate Injection

Eagerly Anticipated FDA-Approved Generic to SOTRADECOL® Provides Safe and Effective Solution for Patients, Bypasses Risks Presented by Lower-Quality Compounded Alternatives

CARLSBAD, Calif. – [Leucadia Pharmaceuticals](#), a U.S. innovator in generic drug products and the commercial sales arm of [Custopharm, Inc.](#), today unveiled the only FDA-approved Sodium Tetradecyl Sulfate (STS) generic. This regulated sclerosing agent is therapeutically equivalent to SOTRADECOL®¹ and is a safe and effective alternative to the use of unapproved compounded products.

Sodium Tetradecyl Sulfate (STS) is used to treat small varicose veins of the lower legs. It is AP rated, bar coded, and does not contain natural rubber latex.

“For years patients have had no good options when seeking an affordable generic alternative to Sotradecol,” said Dr. William Larkins, Chief Executive Officer of Leucadia Pharmaceuticals’ parent company, Custopharm. “As a result, some have turned to compounding pharmacies. Instead of finding a lower cost product they have been met with a ‘Wild West’ of unapproved and unregulated options which can present significant additional risk with no commensurate benefit. Leucadia’s FDA-approved STS now provides a safer alternative while also giving health care providers and health care systems peace of mind.”

Compounded drugs are not FDA-approved and, in some cases, this lower level of oversight has been reportedly linked to sterility problems, microbial outbreaks, and negative patient outcomes.² According to industry analysis, some drugs produced by these compounding pharmacies have put patient safety at risk, resulting in numerous tainted drug lawsuits against both hospitals and individual health care providers.³ The American Bar Association reportedly considers compounding centers to be potentially less legally secure than FDA-approved generic alternatives.⁴

In addition, researchers led by Dr. Mitchel Goldman, past president of the American Society for Dermatologic Surgery (ASDS), and fellow member and past president of the American Vein & Lymphatic Society (formerly the American College of Phlebology), found specific inconsistencies

¹ Sotradecol is a registered trademark of Mylan Pharma Group Limited.

² Gudeman J, Jozwiakowski M, Chollet J, Randell M. *Potential risks of pharmacy compounding*. *Drugs R D*. 2013;13(1):1–8. doi:10.1007/s40268-013-0005-9

³ Gallegos, A. (2013). *Physicians entangled in tainted drugs lawsuits*. [online] Amednews.com. Available at: <https://amednews.com/article/20130211/profession/130219977/2/> [Accessed 12 Oct. 2019]

⁴ Clark, Michael E. (2015) American Bar Association, Health Law Section. *Pharmaceutical and Medical Device Law: Regulation of Research, Development and Marketing (Second Edition)* LCC KF2915.P4 P495 2015 | DDC 344.7304/16--dc23

with STS products made through compounding.⁵ The study found some compounding pharmacies were producing 3 percent sodium tetradecyl sulfate by simple dilution of a 27 percent industrial detergent solution that is not manufactured for use in humans.

“Our investigation found troubling content variability in compounded STS solutions we studied,” said Goldman. “These compounding pharmacies were using a lower-quality ingredient as a starting material, resulting in significant concentrations of a highly toxic contaminant called carbitol. Both patients and physicians need to be aware that the stated concentration of these compounded drugs may not be correct and that potentially harmful contaminants may be present in the solution. Leucadia’s generic STS solves this problem by finally providing a regulated, FDA-approved alternative that patients have been waiting for.”

About Leucadia Pharmaceuticals

At Leucadia Pharmaceuticals, we are poised to be leaders in the generic injectables market. We’re investing heavily, expanding operations and scientific personnel, while also pursuing partnerships and product acquisitions. Our goal is to provide important new generic injectable products to the acute and specialty markets and to reach communities and conditions that are under-served. Leucadia’s products include Pentobarbital Sodium Injection, USP and Valrubicin Intravesical Solution, USP, an FDA-approved equivalent to VALSTAR^{®6}. Leucadia Pharmaceuticals was established in 2015 as the commercial sales arm of Custopharm, Inc., and is associated with Water Street Healthcare Partners. For more information, please visit leucadiapharma.com.

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⁵ Goldman, M. P. (2004), Sodium Tetradecyl Sulfate for Sclerotherapy Treatment of Veins: Is Compounding Pharmacy Solution Safe?. *Dermatologic Surgery*, 30: 1454-1456. doi:10.1111/j.1524-4725.2004.30502.x

⁶ VALSTAR[®] is a registered trademark of Endo International plc or one of its affiliates.