GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Latex Content

This document is in response to your request for information regarding the latex content of Trodelvy® (sacituzumab govitecan-hziy [SG]) for injection, for intravenous use.

Some data may be outside of the US FDA-approved Prescribing Information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA approved prescribing information.

The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.pdf

Relevant Product Labeling[1]

SG is a Trop-2 (trophoblast cell-surface antigen-2) directed antibody and topoisomerase inhibitor conjugate, composed of 3 components: the humanized monoclonal antibody (mAb), hRs7 IgG1k (also called sacituzumab), which binds to Trop-2; the drug SN-38, a topoisomerase inhibitor; and a hydrolysable linker (CL2A), which links the humanized mAb to SN-38.

SG for injection is a sterile, preservative-free, off-white to yellowish lyophilized powder for intravenous use in a 50 mL clear glass single-dose vial, with a rubber stopper and crimp-sealed with an aluminum flip-off cap. No further information regarding latex content is provided in the SG US FDA-approved Product Labeling.

Available Data[2]

SG does not contain latex. Latex is not used in the manufacturing of the drug (SN-38), the linker (CL2A), and/or the SG product vial stopper and it is not a component of any product contact material, equipment, or raw materials used in the production of the humanized mAb.

Formulations data is sourced from the product's manufacturing standards and is intended to provide guidance on the product's formulation. The final product may vary slightly within manufacturing controls.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the Trodelvy US Prescribing Information available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.pdf

Follow-Up

For any additional questions, please contact Trodelvy Medical Information at:

☎ 1-888-983-4668 or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or https://www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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