GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use in Patients on Dialysis

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and its use in patients on dialysis.

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: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Relevant Product Labeling[1]

Clinical Pharmacology

Pharmacokinetics

Specific Populations

Pharmacokinetic analyses in patients treated with SG did not identify an effect of mild renal impairment to moderate renal impairment (CrCl 30–89 mL/min) on the pharmacokinetics of SG. Renal elimination is known to contribute minimally to the excretion of SN-38, the small molecule moiety of SG. There are no data on the pharmacokinetics of SG in patients with severe renal impairment (CrCl 15–29 mL/min), or end-stage renal disease (CrCl <15 mL/min).

Clinical Data in Patients On Dialysis

There are no Gilead studies evaluating the use of SG in patients on dialysis.

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to 08 January 2025, using the search terms of Trodelvy, SG, kidney dialysis, renal dialysis, hemodialysis and related search terms. No relevant data were identified.

References

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

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

Product Label

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

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 Pharmacovigilance and Epidemiology ☎ 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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