GILEAD | Medical Information

Epclusa® (sofosbuvir/velpatasvir) Stomach/Intestinal Absorption Conditions

This document is in response to your request for information regarding the use of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) in patients with conditions that impact stomach and/or intestinal absorption.

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 are available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.

Product Labeling[1]

VEL solubility decreases as pH increases. Drugs that increase gastric pH are expected to decrease concentration of VEL.

There is no information in the SOF/VEL product labeling about the use of SOF/VEL in patients with conditions impacting stomach/intestinal absorption, including bariatric surgery or gastric bypass surgery.

Available Data on SOF/VEL and Stomach/Intestinal Absorption Conditions

There are no Gilead studies that evaluate the use of SOF/VEL in patients with conditions that impact stomach and/or intestinal absorption, including bariatric surgery or gastric bypass surgery.

Please note that SOF/VEL, like most solid oral dosage forms, undergoes dissolution in the stomach. Depending on the part of the stomach or intestine that is impacted, the ability of SOF/VEL to dissolve, be absorbed, or be bioavailable may be compromised.[2]

Case Reports on SOF/VEL and Stomach/Intestinal Absorption Conditions

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[3]

SOF/VEL in multiple absorption issues, including ileostomy[4]

A 31-year-old female patient with a history of alcoholic cirrhosis, who was negative for HCV, underwent a liver transplant from an HCV nucleic acid test-positive donor. Due to rectal bleeding secondary to anal ulcerations and internal hemorrhoids, the patient underwent a surgical intervention at the time of transplantation to create a diverting loop ileostomy. Postoperative complications included pancreatitis and a mucormycosis infection that required an above-the-knee amputation and treatment with IV liposomal amphotericin B.

One month after liver transplantation, the patient experienced a recurrent GI bleed that did not respond to endoscopic intervention and was medically treated with pantoprazole 80 mg IV twice daily. On postoperative Day 3, the patient had a detectable HCV viral load of 39,962,849 IU/mL; however, treatment for HCV was initially delayed due to absorption concerns, including the patient's inability to swallow whole tablets, high ileostomy drain output (2 L per day), GI bleeding, pancreatitis, and decreased absorption of SOF/VEL during concomitant administration of a PPI.

On postoperative Day 39, a 12-week course of SOF/VEL treatment was initiated. SOF/VEL was crushed, mixed with 30 mL of water, and administered through the patient's nasogastric tube once daily, 4 hours before the morning dose of pantoprazole (80 mg) was administered. To assess the efficacy of SOF/VEL, HCV viral loads were monitored weekly, and viral clearance was achieved at Week 4. The patient completed 39 of the planned 84 treatment days before she died due to sepsis on postoperative Day 77. Sustained virologic response at 12 weeks could not be evaluated.

SOF/VEL in Roux-en-Y gastric bypass[5]

A 64-year-old African American male patient with obesity and HCV genotype 1a infection, biomarker testing consistent with F1 to F2 liver damage, received 12 weeks of LDV/SOF treatment in March 2016 and had virologic relapse 3 to 4 months after EOT. The patient reported daily adherence to LDV/SOF and confirmed taking lansoprazole 30 mg once daily for severe gastroesophageal reflux disease while on HCV treatment. He subsequently underwent Roux-en-Y gastric bypass to treat obesity.

In December 2016, the patient initiated 24 weeks of SOF/VEL + ribavirin for HCV retreatment. Although the provider instructed the patient to discontinue lansoprazole, the patient continued taking it during and after SOF/VEL treatment. Although the patient reported no missed doses of SOF/VEL, virologic relapse occurred 3 months after EOT. There was no reported evidence of any reinfection source.

In December 2017, the patient initiated 12 weeks of SOF/VEL/VOX. The patient remained on PPI therapy with esomeprazole 20 mg daily, which he was instructed to take at the same time as SOF/VEL/VOX and with food. The patient was concerned about SOF/VEL/VOX absorption and decided on his own to chew the tablets. HCV RNA levels remained undetectable through 27.5 weeks after EOT.

References

1. Enclosed. Gilead Sciences Inc, EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. DiPiro J, Talbert RL, Yee GC, Matzke G, Wells BG, Posey LM. *Pharmacotherapy: A pathophysiologic approach. Fifth edition.* New York: McGraw-Hill; 2002:962-963.
3. Nissen T, Wynn R. The Clinical Case Report: A Review of Its Merits and Limitations. *BMC research notes.* 2014;7:264. https://www.ncbi.nlm.nih.gov/pubmed/24758689

4. Pluckrose DM, Szczepanik A, Bova SE, Freedman SR. Hepatitis C viral clearance with coadministration of crushed sofosbuvir/velpatasvir and high-dose pantoprazole after liver transplantation. *Am J Health Syst Pharm.* 2022;79.
5. Mod AT, Katz R. Treatment-experienced patient with Roux-en-Y gastric bypass successfully treated with sofosbuvir/velpatasvir/voxilaprevir: A case report. *Am J Health Syst Pharm.* 2023;80(6):343-347.

Abbreviations

EOT=end of treatment
GI=gastrointestinal
LDV=ledipasvir
PPI=proton pump inhibitor
SOF=sofosbuvir
VEL=velpatasvir
VOX=voxilaprevir

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Epclusa US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.

Follow-Up

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

☎1-866-MEDI-GSI (1-866-633-4474) or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or 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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