



Hepcludex[®] (bulevirtide-gmod) Dose Recovery Study

This document is in response to your request for information regarding the dose recovery study conducted for Hepcludex[®] (bulevirtide-gmod [BLV]) for the treatment of chronic HDV infection.

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/hdv/hepcludex/hepcludex_pi.

Product Labeling¹

Indications and Usage

BLV is indicated for the treatment of chronic HDV infection in adults without cirrhosis or with compensated cirrhosis.

This indication is approved under accelerated approval based on a decrease in HDV RNA and ALT normalization. An improvement in disease-related clinical outcomes has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Dosage and Administration

Recommended dosage in adults

The recommended dosage in adults is BLV 8.5 mg once daily administered by subcutaneous injection.

Clinical Studies

Clinical trials in adults with chronic HDV infection without cirrhosis or with compensated cirrhosis

Trial MYR301

The efficacy of BLV once daily in the treatment of adults with chronic HDV infection without cirrhosis or with compensated cirrhosis is based on data through Week 144 from a multicenter, randomized, open-label, parallel-arm phase 3 trial, Trial MYR301 (NCT03852719), in which 100 participants received BLV 8.5 mg once daily. The MYR301 protocol specified the BLV dose as 10 mg; however, a dose recovery study later showed that the delivered dose was 8.5 mg.

Available Data on BLV Dosing

Dose Recovery Studies of Clinical Trial Drug Products²

A dose recovery study was performed to determine the amount of BLV delivered with two 10-mg BLV formulations: BLV 5 mg for injection vials (2 × 5 mg); BLV 10 mg for injection vial (1 × 10 mg). Ten doses of each formulation were prepared as follows: 5 mg BLV for injection from five lots (50 doses tested) of BLV within several clinical studies (one phase 3 study [MYR301], three phase 2 studies [MYR204, MYR203, and MYR202], and GS-US-589-6580); 10 mg BLV for injection from one lot (10 doses tested) of BLV from two clinical studies (GS-US-589-6160 and GS-US-589-6162). Investigators assessed the amounts of BLV held up at each step of the dose reconstitution and preparation process and the final expelled amount. The final amount was measured gravimetrically, and the deliverable volume was calculated using the densities of the respective reconstituted solutions.

The mean (range of individual doses) dose delivered for the BLV 5 mg for injection formulation was 8.81 (8.24–9.57) mg.

The mean (range of individual doses) for the BLV 10 mg for injection formulation was 8.54 (8.38–8.77) mg.

The overall mean (range) BLV content per dose was 8.77 (8.24–9.57) mg.

Dose Recovery and Bioequivalence of Commercial Drug Product²

Three lots of the proposed BLV 10 mg for injection formulation were assessed to determine whether the net container content and volume were equivalent to those of the 5-mg BLV for injection formulation. Ten doses of the 10-mg formulation were prepared and evaluated. The mean (range) BLV content per dose was 8.76 (8.48–9.15) mg. Thus, the commercial preparation of the product was equivalent to that used in clinical studies.

Study GS-US-589-6580 showed that the 1-mL vial of BLV 10 mg injection was bioequivalent to two vials of the 1 mL BLV 5 mg formulation.

References

1. Enclosed. Gilead Sciences Inc. HEPCLUDEX® (bulevirtide-gmod) injection, for subcutaneous use. US 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 Hepcludex US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/hdv/hepcludex/hepcludex_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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