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Hepcludex® (bulevirtide-gmod) Storage and Stability

This document is in response to your request for extended storage and stability information of Hepcludex® (bulevirtide-gmod [BLV]) 8.5 mg lyophilized powder for solution for subcutaneous injection and does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Hepcludex® (BLV) should be stored according to the product label.

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 Labeling[1]

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).

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.

How Supplied/Storage and Handling

BLV for injection 8.5 mg is supplied in a carton of 30 single-dose vials.

Each single-dose vial contains a sterile, preservative-free, white to off-white lyophilized powder or cake. It requires reconstitution prior to administration by subcutaneous injection. The container closure is not made with natural rubber latex.

Store BLV vials at room temperature between 20°C to 25°C (68–77°F), excursions permitted from 15°C to 30°C (59–86°F).

After reconstitution, use vials immediately. Discard unused portion.

Alternative Storage and Stability Information[2]

The table below summarizes data from in-house stability studies regarding the storage of BLV 8.5 mg lyophilized powder for injection under varying conditions. The "acceptable duration" refers to the stability of the BLV 8.5 mg lyophilized powder for injection in the specified packaging and storage condition, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

Table 1. Summary of Extended Stability Data for BLV 8.5 mg Lyophilized Powder for Injection Vial[2]

Storage Conditions	Package Type	Acceptable Duration
50°C (122°F)	BLV 8.5 mg vial lyophilized powder for injection[a]	14 days
-20°C (-4°F)		1 month

[a]Colorless 2R glass vial with grey rubber stopper, sealed with aluminum flip-top cap with a green plastic disc.

Freeze-Thaw Stability Study

A freeze-thaw (-20°C to 25°C [-4°F to 77°F]) stability study demonstrated that BLV 8.5 mg lyophilized powder for injection is stable against positive and negative thermal stress without significant degradation. The freeze-thaw study covered three cycles from -20°C (-4°F) to 25°C (77°F), holding for 24 hours at each -20°C (-4°F) to 25°C (77°F) condition for a total of 3 days for each condition.

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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