GILEAD | Medical Information

Hepcludex® (bulevirtide-gmod) Dosage and Administration

This document is in response to your request for information regarding the dosage and administration information 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 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).

Dosage and Administration

Recommended dosage in adults

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

- BLV should be continued as long as it is associated with a response to treatment. The optimal treatment duration is unknown.
- In all patients, manage the underlying HBV infection as clinically appropriate.
- If a dose is missed, that dose should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and resume the original schedule.

Dose preparation and administration

- See the BLV full Instructions for Use for details on the preparation and administration of BLV.
- Healthcare professionals should train patients or caregivers on the proper reconstitution and administration of BLV and SUBQ injection techniques. Consider preparation and administration of the first dose under healthcare professional supervision.

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Aseptically reconstitute BLV lyophilized powder or cake by adding 1 mL of sterile water for injection to the BLV vial.
- Administer entire contents of vial by SUBQ injection into the upper thigh, lower abdomen, or back of the upper arm (only if administered by a caregiver).
- Use reconstituted product immediately. Do not store for later use.

Please refer to the US FDA-approved prescribing information and instructions for use for detailed administration instructions.

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.

Reference

1. Enclosed. Gilead Sciences Inc. HEPCLUDEX® (bulevirtide-gmod) injection, for subcutaneous use. US Prescribing Information. Foster City, CA.

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

Data Privacy

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