Bulevirtide PK Fact Sheet

Details

Generic Name	Bulevirtide
Trade Name	Hepcludex®
Class	Entry inhibitor (NTCP antagonist)
Molecular Weight	Not available
Structure	Not available (linear peptide)

Summary of Key Pharmacokinetic Parameters

Linearity/non-linearity	Exposure increased disproportionally while the clearance and volume of distribution decreased with higher doses (IV and subcutaneous administration). Non-linear pharmacokinetics followed a two-compartment target-mediated drug disposition model.[1]
Steady state	Assumed to be achieved during the first few weeks of administration.
Elimination half-life	4-7 h.
C_{max}	423 ng/mL, (10 mg sub-cut QD, at steady state).[2]
C_{24}	Not stated.
AUC_{0-24}	1849 h*ng/mL (10 mg sub-cut QD, at steady state).[2]
Tmax	2 h (10 mg sub-cut QD, at steady state).[2]
Bioavailability	85% (subcutaneous administration).[1]
Absorption	No data.
Protein Binding	>99%
Volume of Distribution	Estimated smaller than total body water.
CSF:Plasma ratio	No data.
Renal Clearance	None.
Renal Impairment	No studies have been conducted.
Hepatic Impairment	No studies have been conducted. The use in decompensated liver disease is not recommended.

Metabolism and Distribution

Metabolised by	Degraded to smaller peptides/amino acids as normal protein catabolism.
Inducer of	None expected.
Inhibitor of	OATP1B1/B3, NTCP. CYP3A4 (limited evidence).
Transported by	NTCP.

References

Unless otherwise stated (see below), information is from:
Hepcludex Summary of Product Characteristics, MYR GmbH, August 2021.

1. *Bulevirtide: First Approval. Kang C & Syed YY. Drugs, 2020, 80: 1601-1605.*
2. *Review article: clinical pharmacology of current and investigational hepatitis B virus therapies. Smolders EJ, Burger DM, Feld JJ, & Kiser JJ. Aliment Pharmacol Ther, 2020, 51(2): 231-243.*