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\text{\textsubscript{max}}**  
423 ng/mL, (10 mg sub-cut QD, at steady state).²

**C\text{\textsubscript{24}}**  
Not stated.

**AUC\textsubscript{0-24}**  
1849 h*ng/mL (10 mg sub-cut QD, at steady state).²

**T\text{\textsubscript{max}}**  
2 h (10 mg sub-cut QD, at steady state).²

**Bioavailability**  
85% (subcutaneous administration).²

**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:  
