

Supplementary Material

Article Title: Pharmacokinetics of Viloxazine ER (Viloxazine Extended-Release Capsules) in Breast Milk of Healthy Lactating Women

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DISCLAIMER

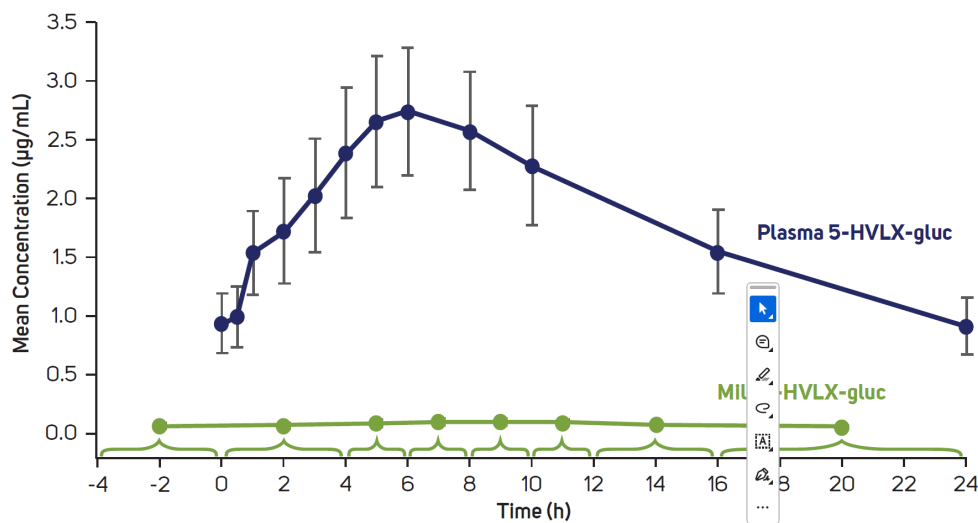
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Supplementary Methods

The study was conducted at a single site: PPD Phase 1 Clinic, Las Vegas, NV, USA. The study was advertised through IRB-approved advertisements and a social media campaign. Viewers who responded to advertisements were contacted by the study site team for a preliminary check of eligibility/schedule for screening.

Supplementary Figure 1: 5-HVLX-gluc mean concentrations in plasma and breast milk

The 5-HVLX-gluc breast milk: plasma ratio at steady-state (day 3) was 0.0391.



Milk and plasma concentration-time profiles of 5-HVLX-gluc. Concentration shown as mean $\pm$ standard deviation. Green brackets indicate pre-specified milk collection time intervals.

Supplementary Table 1 :5-HVLX-gluc pharmacokinetics measured in breast milk and plasma

5-HVLX-gluc pharmacokinetic parameters	Breast milk	Plasma
AUC _{tau} (CV%), h*µg/mL	1.59 (31.2)	42.3 (21.0)
C _{max} (CV%), µg/mL	0.094 (31.1)	2.73 (19.3)
T _{max} , h	9.53	6.00
C _{trough} (CV%), µg/mL	0.048 (33.3)	0.878 (27.3)
C _{ave} (CV%), µg/mL	0.068 (30.7)	1.76 (21.0)
Am _{milk} (CV%), mg/day	0.0357 (48.2)	

Supplementary Table 2: Estimated infant exposure to 5-HVLX-gluc

	5-HVLX-gluc
Daily infant dosage (CV%), mg/day	0.0357 (48.2)
Estimated Daily Infant Dose (CV%), mg/kg/day	
EDID	0.01 (31.1)
EDID (early infancy)	0.01 (31.1)
Relative Infant Dose (CV%), %	
RID	0.114 (38.2)
RID (early infancy)	0.152 (38.2)

EDID and RID are based on estimated (standard) 150 mL/kg/day infant milk intake. EDID and RID in early infancy are based on a higher 200 mL/kg/day estimated milk intake, per FDA guidance of Clinical Lactation Studies. Measurements are geometric mean (geometric mean coefficient of variation, CV%).

N=15. Measurements are geometric mean (geometric mean CV%), with the exception of T_{max} (median).