

Ursodeoxycholic acid PK Fact Sheet

Prepared August 2019

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Details

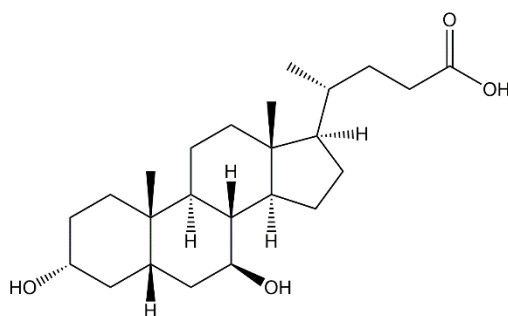
Generic Name Ursodeoxycholic acid

Trade Name Destolit®, Urso®

Class PBC agents

Molecular Weight 392.56

Structure



Summary of Key Pharmacokinetic Parameters

Linearity/non-linearity	Not determined
Steady state	Not determined
Plasma half-life	Not determined
C _{max}	3.4 µM (after 150 mg, single dose) ¹
C ₂₄	Not determined
AUC	8.9 µM x h/L (after 150 mg, single dose) ¹
Bioavailability	Not determined
Absorption	100% oral absorption ²
Protein Binding	96-99% ²
Volume of Distribution	Not determined (expected to be small)
CSF:Plasma ratio	Not determined
Semen:Plasma ratio	Not determined
Renal Clearance	<1%
Renal Impairment	No recommendation
Hepatic Impairment	No recommendation

Metabolism and Distribution

Metabolised by	Glycine/taurine conjugation in the liver
Inducer of	None reported
Inhibitor of	None reported
Transported by	Not reported

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References

Unless otherwise stated (see below), information is from:

Destolit Summary of Product Characteristics, Norgine Ltd., October 2018.

Urso 250 Prescribing Information, Aptalis Pharma US, Inc., June 2013.

1. Modeling and Experimental Studies of Obeticholic Acid Exposure and the Impact of Cirrhosis Stage, Edwards J, LaCerte C, Peyret T, et al. Clin Transl Sci, 2016, 9(6): 328–336.
2. Ocaliva Product Monograph, Intercept Pharmaceuticals, May 2017.