

## Ursodeoxycholic acid PK Fact Sheet

Prepared July 2022

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## Details

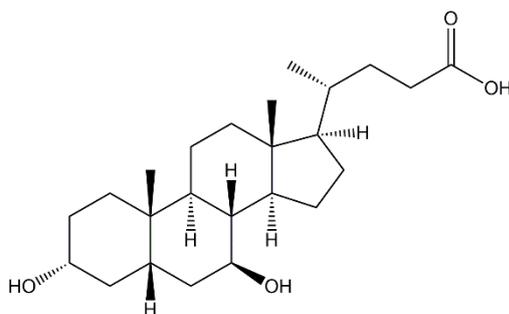
Generic Name Ursodeoxycholic acid

Trade Name Destolit<sup>®</sup>, Urso<sup>®</sup>

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 <sub>max</sub>        | 3.4 μM (after 150 mg, single dose) <sup>1</sup>       |
| C <sub>24</sub>         | Not determined  |
| AUC                     | 8.9 μM x h/L (after 150 mg, single dose) <sup>1</sup> |
| Bioavailability         | Not determined  |
| Absorption              | 100% oral absorption <sup>2</sup>                     |
| Protein Binding         | 96-99% <sup>2</sup>                                   |
| 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.