

Didanosine PK Fact Sheet

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Details

Generic Name Didanosine (ddl) Trade Name Videx®, Videx EC®

Class Nucleoside Reverse Transcriptase Inhibitor

Molecular Weight 236.2

Structure

Summary of Key Pharmacokinetic Parameters

Didanosine is enzymatically converted to dideoxyadenosine-triphosphate (ddATP), its active metabolite.

Linearity/non-linearity Increases in plasma concentrations were dose proportional over the range of 50-400 mg.

Plasma half life ~1.4 h

Cmax 933 ± 434 ng/ml (400 mg once daily, Videx EC) 2432 ± 919 ng/ml.h (400 mg once daily, Videx EC) AUC

Bioavailability ~42% (following single dose of buffered formulation)

To minimise the impact of food, Videx gastro-resistant capsules should be administered on an Absorption

empty stomach at least 2 hours before or 2 hours after a meal.

Protein Binding <5% 54 L Volume of Distribution

CSF:Plasma ratio ~21% of corresponding plasma concentration.

Semen:Plasma ratio Median didanosine concentrations have been found to be greater in semen than in plasma:

455 ng/ml (range <50-2190 ng/ml) in seminal plasma and <50 (range <50-860 ng/ml) in blood.

Large interindividual variability was noted [1].

~20% Renal Clearance

Half-life of didanosine after oral administration increased from an average of 1.4 hours in Renal Impairment

> subjects with normal renal function to 4.1 hours in subjects with severe renal impairment requiring dialysis. Patients with a creatinine clearance <60 ml/min may be at greater risk of didanosine toxicity due to decreased drug clearance. A dose reduction is recommended for

these patients.

Hepatic Impairment Metabolism of didanosine may be altered in patients with severe hepatic impairment. No

specific dose adjustment can be recommended.



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Metabolism and Distribution

Metabolised by Xanthine oxidase.

Thought to follow the same pathways responsible for elimination of endogenous purines.

Inducer of N/A
Inhibitor of N/A

Transported by Unknown

References

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

Videx® Summary of Product Characteristics, Bristol-Myers Squibb.

Videx®US Prescribing Information, Bristol- Myers Squibb.

1. Cruciani M, Liuzzi G, Chirianni A, et al. Penetration of didanosine in semen of HIV-1-infected men. J Antimicrob Chemother. 2006;57(6): 1244-1247.