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*APPLICATION NUMBER:*

**21-333**

**CLINICAL PHARMACOLOGY AND  
BIOPHARMACEUTICS REVIEW(S)**



clinically effective antidiuretic doses are usually below threshold levels for effects on vascular or visceral smooth muscle.

Minirin administered intranasally has an antidiuretic effect about one-tenth that of an equivalent dose administered by injection.

**Pharmacokinetics**

Intranasal Minirin is absorbed rapidly from the nasal mucosa. Minirin exhibits a biphasic elimination profile, with half-lives of 7.8 and 75.5 minutes for the initial and terminal phases, respectively, in contrast to lysine vasopressin, which has initial and terminal phase half-lives of 2.5 and 14.5 minutes, respectively.

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