



[REDACTED] [REDACTED]	<i>KETOCONAZOLE</i>
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All redactions
under Section 41
and Section 43 of
the Freedom of
Information Act.

KETOCONAZOLE

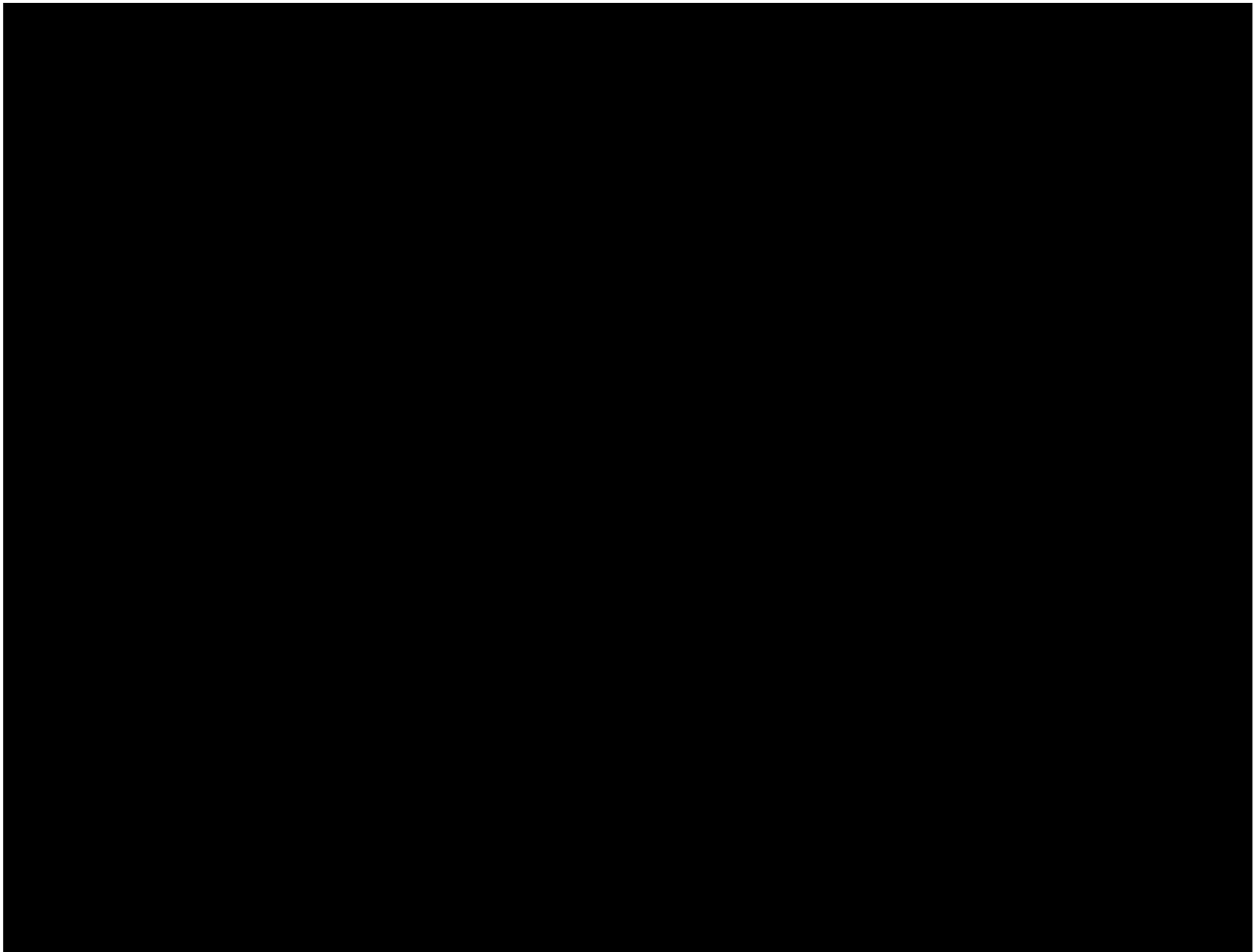
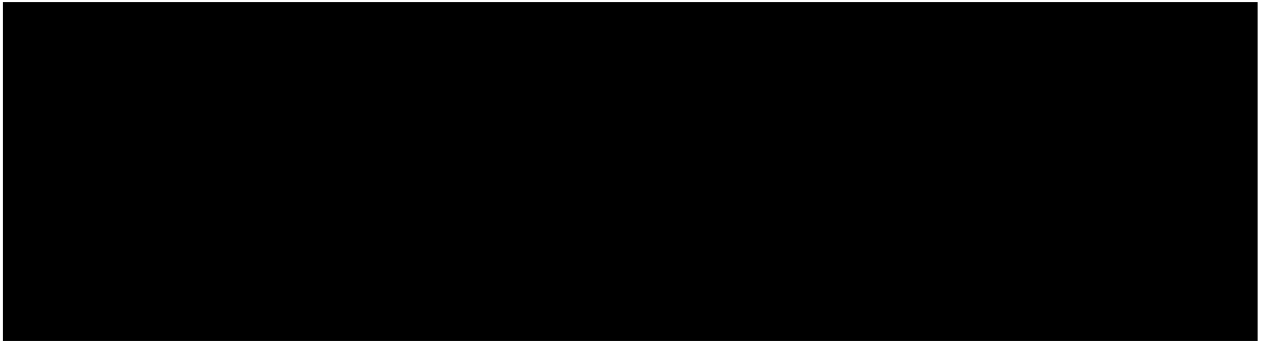
shampoo 2%

2.6.4 Pharmacokinetics written summary

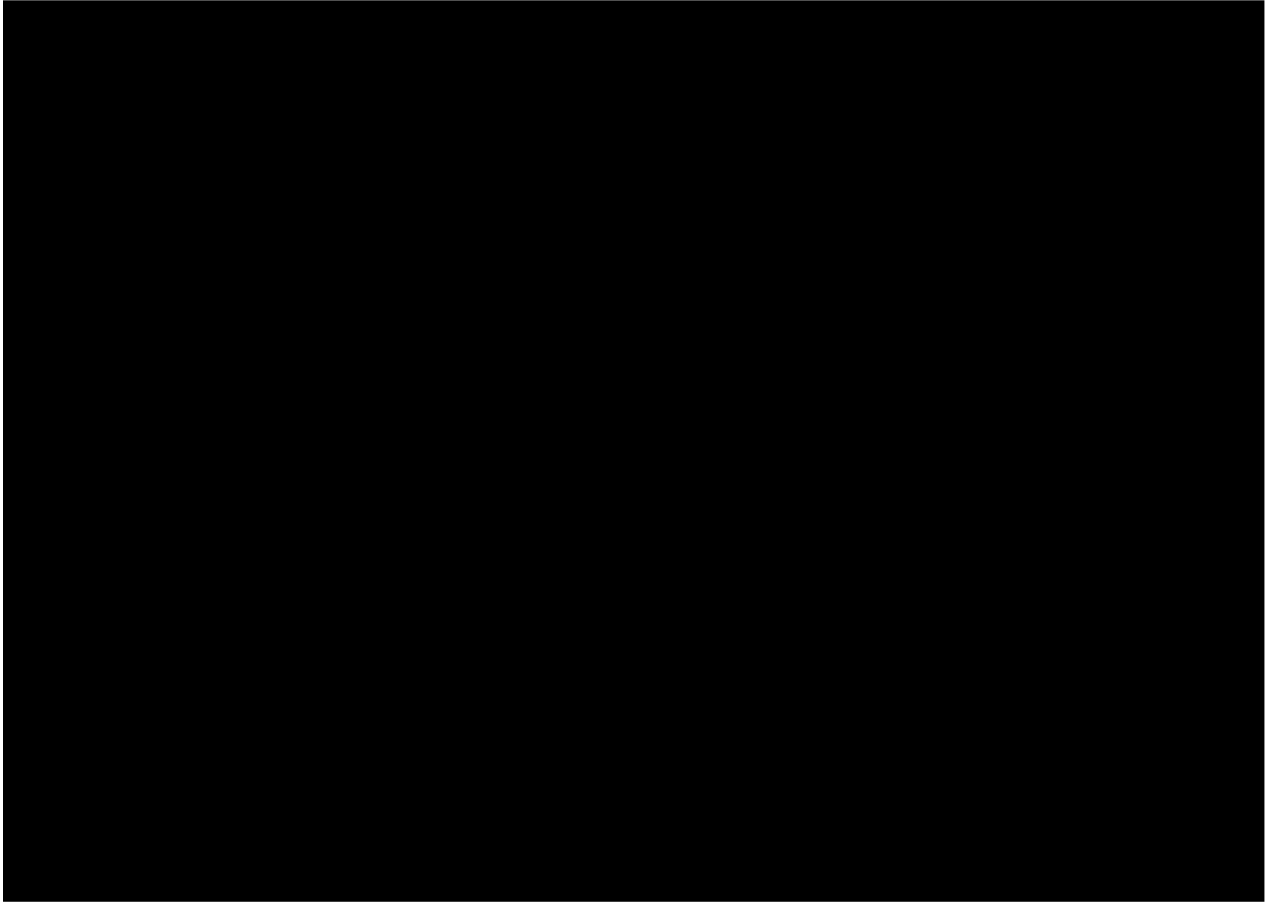
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2.6.4 Pharmacokinetics written summary

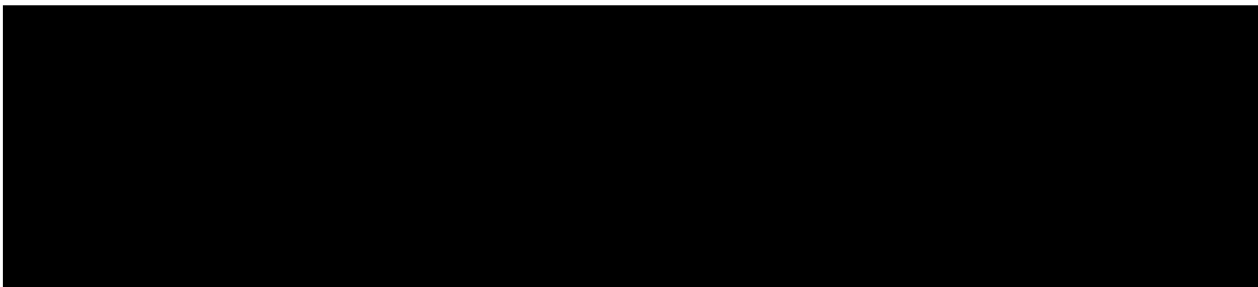
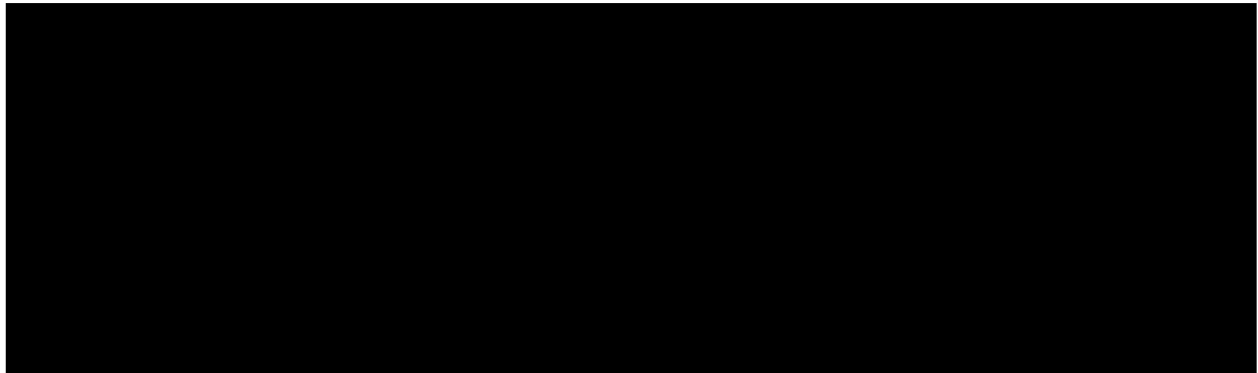
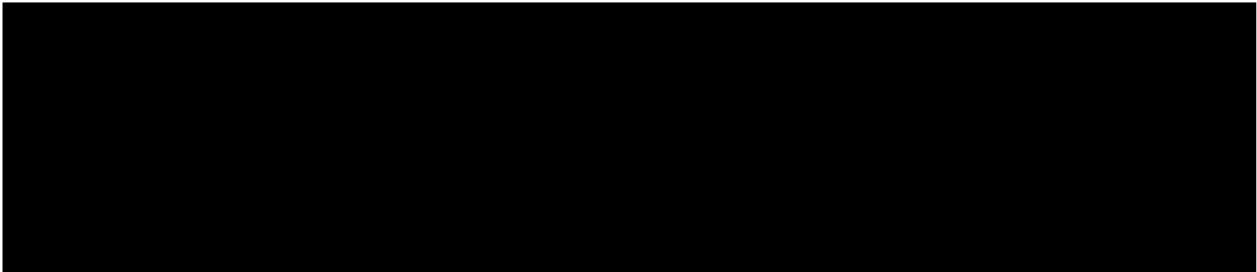
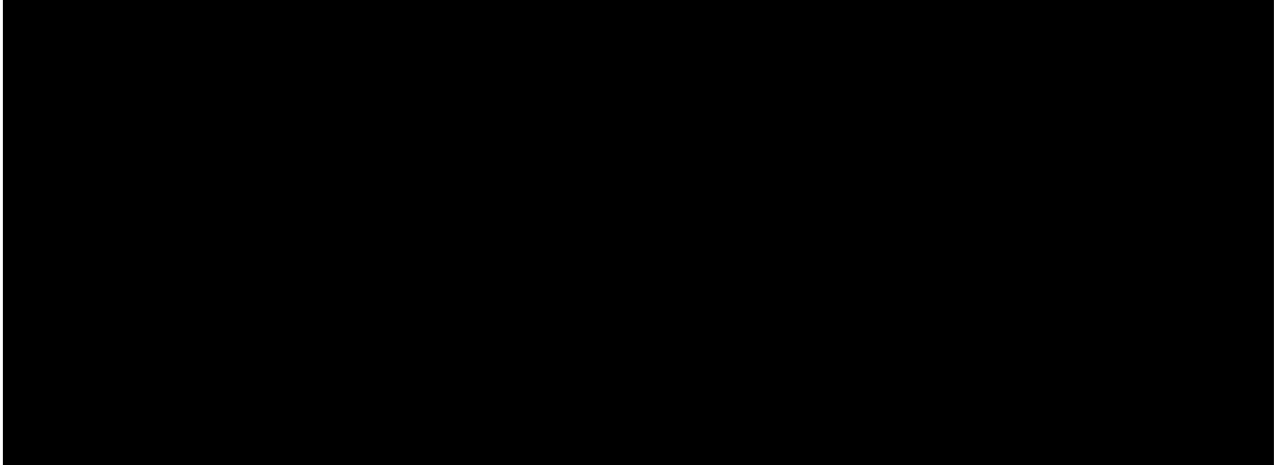
Analytical Methods and Validation Reports





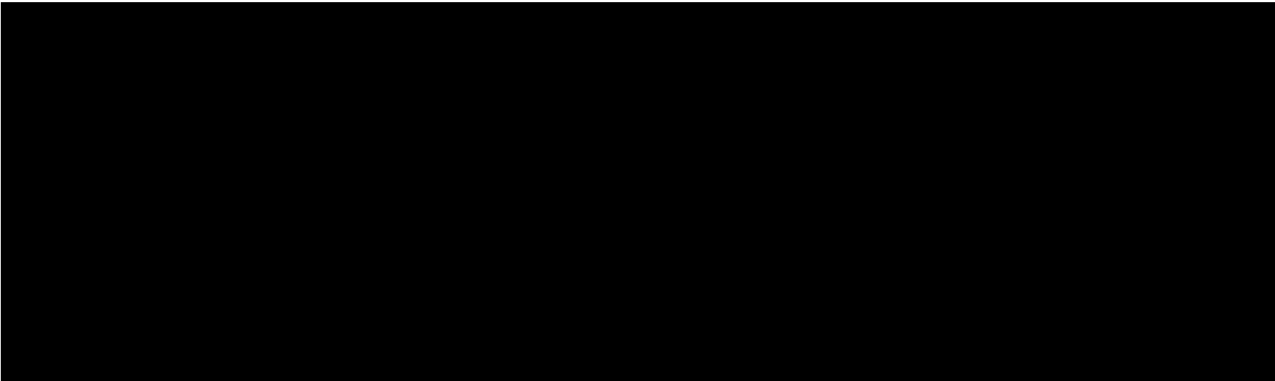
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Absorption

Ketoconazole applied topically as shampoo or cream, has negligible systemic absorption. Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use (Schäfer-Korting, 1989).

Distribution

Following chronic or single application with 2% ketoconazole shampoo, plasma concentrations of ketoconazole were undetectable with no hepatic function test abnormalities.

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole 2% shampoo on the scalp. Plasma levels were detected after topical administration of ketoconazole 2% shampoo on the whole body (SmPC Nizoral 2% shampoo, Thornton & Ross Ltd. UK, 23/10/2020).

Metabolism

Ketoconazole is not absorbed systemically after topical administration (Daneshmend and Warnock, 1988).

Excretion

Not applicable.

Pharmacokinetic Drug Interactions (non-clinical)

Van Tyle, et al investigated drug interactions of ketoconazole, and concluded that Ketoconazole has several reported drug interactions, including lower bioavailability with cimetidine, accumulation of cyclosporin during concurrent therapy and a possible disulfiram-like reaction with alcohol (Van Tyle, et al 1984).

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Since Ketoconazole is not absorbed systemically after topical administration (Daneshmend and Warnock, 1988), no drug interactions or adverse effects are expected.

Other Pharmacokinetic Studies

Not applicable.