

## TABLE OF CONTENTS

1	SUMMARY OF THE ASSESSMENT .....	3
2	INTRODUCTION.....	4
3	SUBSTANCE INFORMATION .....	4
4	NON-CLINICAL SAFETY DATA .....	6
4.1	Pharmacodynamics.....	6
4.2	Acute toxicity .....	6
4.3	Repeated dose toxicity.....	7
4.4	Genotoxicity.....	7
4.5	Carcinogenicity .....	7
4.6	Reproductive and developmental toxicity .....	7
4.7	Pharmacokinetics.....	7
5	CLINICAL SAFETY DATA .....	7
5.1	Therapeutic use .....	7
5.2	Dosage and administration .....	7
5.3	Clinical adverse effects .....	7
5.4	Hypersensitivity .....	7
5.5	Pharmacokinetics.....	8
6	PDE DERIVATION.....	8
6.1	Critical effects .....	8
6.2	Rationale for the derivation.....	8
7	CONCLUSION .....	11
8	REFERENCES.....	12
	ANNEX 1: GLOSSARY.....	13
	ANNEX 2: SEARCH STRATEGY.....	14
	ANNEX 3: SUMMARY OF THE EXPERT CVs .....	15

The report is valid for 3 (three) years as of the date of the assessment review data.

Reproduction or unauthorized distribution is strictly prohibited. The present document is provided to a single organization and may not be resold, copied, or redistributed to other companies. The use by any company other than the one indicated in the watermark is prohibited.