

IMP Name/code

IB Edition N.

Release date:

Product Code:

Product Name:

INVESTIGATOR'S BROCHURE

Edition Number:

Release Date:

Cut-off Date:

Replaces previous Edition N.____ dated _____

IMP Name/code

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Release date:

The information contained in this document is property of <XXXXXX> and is strucly confidential

SIGNATURE PAGE

This Investigator's Brochure was subject to a critical review and its release was approved by:

Name: _____ Role: _____

Signature: _____

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(date)

CLINICAL R&D DIRECTOR

Name: _____ Role: _____

Signature: _____

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(date)

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SUMMARY OF CHANGES IMPLEMENTED IN THE IB

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APPENDICES (if any)

** Literature references (i.e. publications and/or reports) should be mentioned at the end of each chapter where appropriate.*

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1. LIST OF ABBREVIATION

2. SUMMARY

2.1 General Overview

<Brief summary highlighting the significant physical, chemical, pharmaceutical information >

2.2 Non-clinical studies

1.2.1 Pharmacology

1.2.2 Pharmacokinetics & Metabolism

1.2.3 Toxicology

2.3 Human studies

1.3.1 Pharmacokinetics

1.3.2 Safety And Tolerability

1.3.3 Efficacy

3. INTRODUCTION

< Chemical class; Product Name/Code; proposed pharmacological class>

<Expected position within the proposed pharmacological class; rationale for performing research with the IMP; anticipated prophylactic, therapeutic or diagnostic indication(s)>

<Introductory statement providing the general approach to be followed in evaluating the IMP>

4. PHYSICAL, CHEMICAL, AND PHARMACEUTICAL PROPERTIES AND FORMULATION

4.1 Active Substance

4.1.1 Physical-Chemical Characteristics

< Composition and characteristics of active ingredient, appearance, molecular formula, chemical name, molecular weight, CAS number, INN, INN.M, structural formula, solubility>

4.1.2. Manufacturing

<The active pharmaceutical ingredient XXX is manufactured in accordance to GMP regulationby: name and address of the manufacturer>

4.2 Investigational Product

4.2.1. Formulation

<Description of the formulation(s) to be used, including excipients; structural similarity to other known compounds >

4.2.2. Manufacturing

4.2.3. Stability, Storage and usage

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< no details on specific stability studies>

5. NON-CLINICAL STUDIES

5.1. Non-clinical Pharmacology

<Summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals.

Include studies to assess potential therapeutic activity (e.g. efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)).

5.1.1. Mechanism of action

5.1.2. In vitro Pharmacology

5.1.3. In vivo pharmacology

5.2 Pharmacokinetics and Product Metabolism in Animals

<Summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied.

Discussion of the absorption and the local and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species>

5.2.1. In vitro Studies

5.2.2. In vivo Studies

5.3 Toxicology

<Summary of the toxicological effects found in studies conducted in different animal species>

5.3.1 Single dose

5.3.2. Repeated dose

5.3.3. Special studies

5.3.4. Reproductive toxicity

5.3.5. Genotoxicity (mutagenicity)

5.3.6. Carcinogenicity

6. EFFECTS IN HUMANS

6.1. Summary of complete/discontinued clinical trials

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6.2. Summary of the ongoing clinical trials

6.3. Pharmacokinetics and product metabolism in humans

<Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).

Bioavailability (absolute, where possible, and/or relative) using a reference dosage form.

Population subgroups (e.g., gender, age, and impaired organ function).

Interactions (e.g., product-product interactions and effects of food).

Other pharmacokinetic data (e.g., results of population studies performed within clinical trials)>

6.3.1. Pharmacokinetics in healthy volunteers

6.3.1.1. Single dose

6.3.1.2. Repeated Dose

6.3.2. Pharmacokinetics in Patients

6.4. Safety and tolerability

<Where a number of clinical trials have been completed, provide summaries of safety across multiple trials by indications in subgroups.

Provide tabular summaries of adverse drug reactions for all clinical trials. Important differences in adverse drug reaction patterns/incidences across indications or subgroups should be discussed>

6.5. Efficacy

<Where a number of clinical trials have been completed, provide summaries of efficacy across multiple trials by indications in subgroups>

6.6. Marketing Experience

<Identify countries where the investigational product has been marketed/approved and countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

Summarised any significant information arising from the marketed use>

7. SUMMARY OF DATA AND GUIDANCE FOR THE INVESTIGATOR (Reference Safety Information)

<Provide an overall discussion of the nonclinical and clinical data, and summarise the information from various sources on different aspects of the investigational product to provide the investigator with the most informative interpretation of the available data. Discuss published reports on related product, if appropriate.

Describe possible risks and adverse reactions and specific tests, observations, and precautions that may be needed for a clinical trial.

Provide guidance on the recognition and treatment of possible overdose and adverse drug reactions>

APPENDICES (if any)