FOOD AND DRUGS AUTHORITY

SUMMARY OF PRODUCT CHARACTERISTICS

Document No:	**FDA/DRI/DER/TP-SPC/2013/03**
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ACKNOWLEDGEMENT

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1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s):>

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

<The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>
<The tablet can be divided into equal halves.>
<The tablet should not be divided.>

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>>.>

4.2 Posology and method of administration

Posology

Paediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.>
<No data are available.> <Currently available data are described in section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

<{X} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).>

<There is no relevant use of {X} <in the paediatric population> <in children aged {x to y} <years>, <months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication...>

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

<{X} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication...> (see section 4.3).>

Method of administration

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>
<Interaction studies have only been performed in adults.>

4.6 Pregnancy and lactation

[For Pregnancy and lactation statements see Appendix 3 (ref.Appendix I).]
<Women of childbearing potential>
<Contraception in males and females>
<Pregnancy>
<Breastfeeding>
<Fertility>

4.7 Effects on ability to drive and use machines

<{Invented name} has <no <or negligible> influence> <minor influence>, <moderate influence> <major influence> on the ability to drive and use machines.>
<No studies on the effects on the ability to drive and use machines have been performed.>
<Not relevant.>

4.8 Undesirable effects

[MedDRA frequency convention and system organ class database, see Appendix 3 (ref. Appendix III]

<Paediatric population>

4.9 Overdose

<No case of overdose has been reported.>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code}

<Mechanism of action>
<Pharmacodynamic effects>
<Clinical efficacy and safety>
<Paediatric population>

5.2 Pharmacokinetic properties

<Paediatric population>

5.3 Preclinical safety data

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.>
<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.>
<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

<Not applicable.>
<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>
<This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.>

6.3 Shelf life

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years>

< Shelf life for the reconstituted product, where appropriate...>

6.4 Special precautions for storage

[For storage conditions statements see Appendix 3 (ref. Appendix III)]

<For storage conditions of the <reconstituted> <diluted> medicinal product, see section 6.3.>

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

6.6 Special precautions for disposal <and other handling>

<No special requirements.>

<Any unused product or waste material should be disposed of in accordance with local requirements.>

7. <SUPPLIER>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

8. DATE OF PUBLICATION OR REVISION

1 APPENDIX

1.1 Change History

SN	Date	Ver. No.	Description of Change (section)
1.	Effective date	01	Initial issue