<text> signifies text to be selected or deleted as appropriate.

{text} refers to information to be added]

* + 1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

* + 1. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s):>

For a full list of excipients, see Section 6.1.

* + 1. 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>

* + 1. CLINICAL PARTICULARS
  1. Therapeutic indications

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

* 1. 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>

<{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

* 1. Contraindications

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

* 1. Special warnings and precautions for use
  2. Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed>

<Interaction studies have only been performed in adults>

* 1. Pregnancy and lactation

<Women of childbearing potential>

<Contraception in males and females>

<Pregnancy>

<Breastfeeding>

<Fertility>

* 1. 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>

* 1. Undesirable effects

<Paediatric population>

* 1. Overdose

<No case of overdose has been reported>

* + 1. PHARMACOLOGICAL PROPERTIES
  1. Pharmacodynamic properties

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

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Paediatric population>

* 1. Pharmacokinetic properties

<Paediatric population>

* 1. 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:>

* + 1. PHARMACEUTICAL PARTICULARS
  1. List of excipients
  2. Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other pharmaceutical products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.>

* 1. Shelf life

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

* 1. Special precautions for storage

[For storage condition statements see NDA guidance on labelling]

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

* 1. Nature and contents of container <and special equipment for use, administration or implantation>

<Not all pack sizes may be marketed.>

* 1. 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.>

* + 1. APPLICANT/SUPPLIER

{Name and address}

<{tel}>

<{fax}>

<{email}>

* + 1. WHO PREQUALIFICATION REFERENCE NUMBER
    2. DATE OF <PREQUALIFICATION> / <RENEWAL OF PREQUALIFICATION>

<{DD/MM/YYYY}> <{DD month YYYY}>

* + 1. DATE OF REVISION OF THE TEXT

{MM/YYYY}