**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE**

*[Should the product to which a completed summary of product characteristics (SmPC) be prequalified, it will form Part 4 of the WHO Public Assessment Report that will be posted on the website of the WHO Prequalification Team: medicines (PQTm).*

*Please also consult the prequalification guidance documents:* Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR) *and* Annotated Summary of Product Characteristics (SmPC) Template *and* Ensuring Consistency Between Product Information Documents.

*<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]](#footnote-1)

**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>>.>

* 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

**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**

*[See prequalification guidance:* Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR).*]*

<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.>

* 1. **Undesirable effects**

*[See prequalification guidance:* Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR).*]*

*<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> <...>

**6.4 Special precautions for storage**

*[For storage condition statements see prequalification guidance* Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR).*]*

<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.>

**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. <APPLICANT/SUPPLIER>**

{Name and address}

<{tel}>

<{fax}>

<{email}>

**8. WHO PREQUALIFICATION REFERENCE NUMBER**

**9. DATE OF <PREQUALIFICATION> / <RENEWAL OF PREQUALIFICATION>**

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

**10. DATE OF REVISION OF THE TEXT**

{MM/YYYY}

**Reference list**

*[This list provides references to relevant WHO guidelines and to relevant literature and databases, in addition to the SmPC(s) of the innovator product(s). The list is compiled by WHO.]*

Detailed information on this medicinal product is available on PQTm’s website (see: <http://www.who.int/prequal>).

1. Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility. Throughout a WHOPAR the proprietary name is given as an example only. [↑](#footnote-ref-1)