Template: Summary of Products Characteristics (SmPC)

<text> signifies text to be selected or deleted as appropriate while {text} refers to information to be added.

1. NAME OF THE MEDICINE

{(Invented) name strength pharmaceutical form}

<Herbal Medicine> <Homeopathic Medicine> <Vaccine> <Biological>

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...>

<{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

<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

<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 medicine must not be mixed with other medicines.>

<This medicine must not be mixed with other medicines 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 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>

<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. MARKETING AUTHORISATION HOLDER

{Name and address}
<{tel}>
<{fax}>
<{email}>

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}>

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>

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