SUMMARY OF PRODUCT CHARACTERISTICS

[NOTE: the following are those items of information required by Article 11 of Directive 2001/83/EC, as amended, and current practice in the centralised procedure. This guidance should be read in conjunction with the relevant guidelines that can be found on the EMEA website (See also “Convention” for format and layout): http://www.ema.eu.int/htms/human/qrd/qrdplt/qrdconvention.pdf, in particular the “Guideline on Summary of Product Characteristics” as published on the Website of the European Commission in the Notice to Applicants, Volume 2C: http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm

During the evaluation process, applicants may present SPCs for different strengths in one document, clearly indicating with grey-shaded titles the strength or presentation to which alternative text elements refer. However, a separate SPC per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned will have to be provided by the applicant as follows:

- English language version: immediately after adoption of the opinion.
- All other language versions: at the latest 22 days after adoption of the opinion (i.e. at the latest after incorporation of Member States comments).


Standard statements are given in the template, which must be used whenever they are applicable. If the applicant needs to deviate from these statements to accommodate product-specific requirements, alternative or additional statements will be considered on a case-by-case basis.

Bracketing convention:
{text}:Information to be filled in
<text>:Text to be selected or deleted as appropriate]
1. **NAME OF THE MEDICINAL PRODUCT**

{(Invented) name strength pharmaceutical form}

[no ® ™ symbols attached here and throughout the text; “tablets” and “capsules” in the plural.]

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

[Name of the active substance(s) in the language of the text.]

[Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used. See also the “Guideline on excipients” as published on the Website of the European Commission in the Notice to Applicants, Volume 3B http://pharmacos.eudra.org/F2/eudralex/vol-3/home.htm.]

<Excipient(s):>

For a full list of excipients, see section 6.1.

3. **PHARMACEUTICAL FORM**

[The pharmaceutical form should be stated according to the full “Standard Terms” published by the Council of Europe, in the singular. Where the Council of Europe short standard term is used on small immediate packaging materials, the short term should be added in brackets.]

[Include here a description of the visual appearance of the product pharmaceutical form as marketed, including information on pH and osmolarity as required. Information on appearance of reconstituted parenteral solution should appear under section 6.6.]

<The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The tablet can be divided into equal halves.>

4. **CLINICAL PARTICULARS**

4.1 Therapeutic indications

[Specify, if appropriate <This medicinal product is for diagnostic use only.>

If applicable, results of clinical trials to appear under section 5.1.]

4.2 Posology and method of administration

[In case of restricted medical prescription start this section by specifying the conditions.

Method of administration: directions for proper use by healthcare professionals or by the patient. Further practical details for the patient can be included in the package leaflet, e.g. in the case of inhalers, subcutaneous self-injection.

Instructions for preparation are to be placed under section 6.6 or 12, and cross-referenced here.]

<{(Invented) name} is not recommended for use in children <above> <below> {age Y} due to <a lack of> <insufficient data on <safety> <and> <or> <efficacy> <(see section <5.1> <5.2>)>.>

<The experience in children is limited.>

<There is no experience in children> <(see section <4.4> <5.2>)>.

<There is no relevant indication for use of {(Invented) name} in children.>

<{(Invented) name} is contraindicated in children (see section 4.3).>
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 I.]

[Results from reproduction toxicology to be included under section 5.3 and cross-referenced here, if necessary.]

4.7 Effects on ability to drive and use machines

<Invented name> has <<no> or negligible> influence> <<minor or moderate influence> <major influence>
on the ability to drive and use machines.> [describe effects where applicable]
<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 II.]

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

4.9 Overdose

[Describe the symptoms, emergency procedures, and antidotes (if available) in case of overdose.]

<No case of overdose has been reported.>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group [lowest available level]}, ATC code: {code}

[For products approved under “conditional approval”, include the following statement:]
<This medicinal product has been authorised under a so-called “conditional approval” scheme. This means that further evidence on this medicinal product is awaited. The European Medicines Agency (EMEA) will review new information on the product every year and this SPC will be updated as necessary.>

[For products approved under “exceptional circumstances”, include the following statement:]
<This medicinal product has been authorised under “Exceptional Circumstances”. This means that due to <the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product. The European Medicines Agency (EMEA) will review any new information which may become available every year and this SPC will be updated as necessary.>
5.2 Pharmacokinetic properties

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.>
<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

[Each to be listed on a separate line according to the different parts of the product.] [Name of the excipient(s) in the language of the text.]

6.2 Incompatibilities

<Not applicable.> [if applicable, e.g. for solid oral pharmaceutical forms.] <In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.> [e.g. for parenterals.]
<This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.>

6.3 Shelf life

[Information on the finished product shelf life and on the in-use stability after 1st opening and/or reconstitution/dilution should appear here. Only one overall shelf life for the finished product is to be given even if different components of the product may have a different shelf life (e.g. powder & solvent).]
<..> <6 months> <..> <1 year> <18 months> <2 years> <30 months> <3 years> <..>

6.4 Special precautions for storage
[For Storage condition statements see Appendix III.]
[General storage conditions of the finished product should appear here, together with a cross-reference to section 6.3 where appropriate: <For storage conditions of the <reconstituted> <diluted> medicinal product, see section 6.3>]

6.5 Nature and contents of container

[All pack sizes must be listed. If applicable, add:]
<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal

[Include practical instructions for preparation and handling of the product including disposal of the medicinal product, and waste materials derived from the used medicinal product.]
<No special requirements.>
<Any unused product or waste material should be disposed of in accordance with local requirements.>
7. MARKETING AUTHORISATION HOLDER

[Country name in the language of the text. Telephone, fax numbers or-e-mail addresses may be included (no websites, no e-mails linking to websites).]

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

8. MARKETING AUTHORISATION NUMBER(S)

[Item to be completed by the Marketing Authorisation Holder once the Marketing Authorisation has been granted.]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

[Item to be completed by the Marketing Authorisation Holder once the Marketing Authorisation has been granted or renewed. The date should correspond to the initial authorisation of the medicinal product concerned. It should not reflect individual strength/presentation approvals introduced via subsequent variations and/or extensions. Both the date of first authorisation and, if the authorisation has been renewed, the date of the (last) renewal should be stated in the format given in the following example:
Date of first authorisation: 3 April 1985.
Date of last renewal: 3 April 2000.]

10. DATE OF REVISION OF THE TEXT

[Item to be completed by the Marketing Authorisation Holder at time of printing once a change to the SPC has been approved e.g. the latest Commission Decision, implementation date of the Urgent Safety Restriction or date of EMEA letter/notification.]

{MM/YYYY}

[It is recommended that the following reference to the WHO PQ Website is included:]

<Detailed information on this product is available on the website of the WHO Prequalification program http://www.who.int/prequal>