

FOOD AND DRUGS AUTHORITY

SUMMARY OF PRODUCT CHARACTERISTICS

**TO BE SUBMITTED AS AN ELECTRONIC COPY**

CONFIDENTIAL

IMMUNOLOGICALTERINARY MEDICINAL PRODUCTS

THE CHIEF EXECUTIVE OFFICER,

FOOD AND DRUGS AUTHORITY

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**Document Revision History**

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| --- | --- | --- | --- |
| **SN** | **Date** | **Ver. No.** | **Description of Change (section)** |
| 1. | 1st February 2013 | 01 | Initial issue |
| 2 | 8th January 2024 | 02 | General review of the template in line with the current structure |
| 3 | 30th August 2024 | 03 | 1. Changed the term “supplier” to “Marketing Authorization Holder. 2. Revision of Section 8 from “Date of Publication or Revision” to “Marketing Authorization Number 3. Introduction of Section 9 and 10. |

**NB:** This is a controlled document that has editing restrictions. The editable sections are highlighted. (see starting from page 4).

# ACKNOWLEDGEMENT

The Food and Drugs Authority (FDA) acknowledges the technical support of the World Health Organization (WHO) in the development of this guideline.

# NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form} \*

# QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s):>

For a full list of excipients, see section 6.1.

# 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.>

# CLINICAL PARTICULARS

## Therapeutic indications

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged

{x to y}> <years> <months>>.>

## 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

## Contraindications

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

## Special warnings and precautions for use

* 1. **Interaction with other medicinal products and other forms of interaction**

<No interaction studies have been performed.>

<Interaction studies have only been performed in adults.>

## 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>

## 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.>

## Undesirable effects

*[MedDRA frequency convention and system organ class database, see* [*Appendix 3*](http://www.emea.eu.int/htms/human/qrd/qrdplt/544203en.doc) *(ref. Appendix III]*

*<Paediatric population>*

## Overdose

<No case of overdose has been reported.>

# PHARMACOLOGICAL PROPERTIES

## Pharmacodynamic properties

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

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Paediatric population>

## Pharmacokinetic properties

*<Paediatric population>*

## 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:>

# PHARMACEUTICAL PARTICULARS

## List of excipients

* 1. **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.>

## Shelf life

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

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

## Special precautions for storage

*[For storage conditions statements see* [*Appendix 3 (ref. Appendix III*](http://www.emea.eu.int/htms/human/qrd/AppIIIs6/2927703en.pdf)*)]*

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

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

* 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.>

# MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

# MARKETING AUTHORISATION NUMBER

# DATE OF FIRST AUTHORIATION OR RENEWAL

# DATE OF REVISION OF THE TEXT