**1. Name of the Veterinary Pharmaceutical Product**

**2. Qualitative and Quantitative Composition**

**API<s>:**

**<Excipient(s):>**

For a full list of excipients, see section 6.1.

**3. Pharmaceutical Form**

It shall mean the form in which the product is presented.

3.1 The description of pharmaceutical form should include a full visual description of the appearance of the product e.g. colour, shape, markings and other relevant features.

**4. Clinical Particulars**

4.1 Target species

4.2 Indications for use, specifying the target species

4.3 Contraindications

<None>

<Do not use in...>

<Do not use in case of hypersensitivity to the active substance(s) <, <or to any of the excipient(s).>

4.4 Special warnings <for each target species>

4.5 Special precautions for use

i)Special precautions for use in animals

ii)Special precautions to be taken by the person administering the veterinary Pharmaceutical product to animals

4.6 Adverse reactions (frequency and seriousness)

4.7 Use during pregnancy, lactation or lay

4.8 Interaction with other Pharmaceutical products and other forms of interaction

4.9 Amounts to be administered and administration route

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

4.11 Withdrawal period(s)

Meat and offal><Milk><Eggs>: {X} <hours><days

**5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: {group}, ATCvet code: {lowest available level (e.g. subgroup for chemical substance)}

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

**6.2 Incompatibilities**

In the absence of compatibility studies, this veterinary Pharmaceutical product must not be mixed with other veterinary Pharmaceutical products.

**6.3 Shelf life**

1. Shelf-life of the veterinary Pharmaceutical product as packaged for sale.
2. Shelf-life after first opening the immediate packaging.
3. Shelf-life after dilution or reconstitution according to directions where applicable.
4. Shelf life after incorporation into meal or pelleted feed where applicable.

**6.4. Special precautions for storage**

1. Do not store above <25 °C/30 °C
2. Store below <25 °C/30 °C
3. Store in a refrigerator (2 °C – 8 °C)
4. Store and transport refrigerated (2 °C – 8 °C)
5. Protect from light

**6.5 Nature and composition of immediate packaging**

<Not all pack sizes may be marketed.>

**6.6** **Special precautions for the disposal of unused veterinary Pharmaceutical product or waste materials derived from the use of such products**

<Any unused veterinary Pharmaceutical product or waste materials derived from such veterinary Pharmaceutical products should be disposed of in accordance with local requirements.>

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

{Name and address}

Tel:

Fax:

E-mail:

**8. REGISTRATION NUMBER(S)**

**9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION**

<{DD/MM/YYYY}> <{DD month YYYY}>…

**10 DATE OF REVISION OF THE TEXT**

{MM/YYYY} or <month YYYY>