



MINISTERIO  
DE SANIDAD, SERVICIOS SOCIALES  
E IGUALDAD

**am** agencia española de  
medicamentos y  
productos sanitarios

DEPARTAMENTO DE  
MEDICAMENTOS  
VETERINARIOS

# Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8  
28022 – Madrid  
España

DECENTRALISED PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A  
VETERINARY MEDICINAL PRODUCT**

**Enrocill 50 mg/ml solution for injection for calves, pigs  
and dogs**

**CORREO ELECTRÓNICO**

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## MODULE 1

### PRODUCT SUMMARY

EU Procedure number	ES/V/0208/001/DC
Name, strength and pharmaceutical form	Enrocill 50 mg/ml solution for injection
Applicant	Hifarmax, Lda, Av. Marechal Craveiro Lopes nº96 R/C Dto 2775-696 Carcavelos, Portugal
Active substance(s)	Enrofloxacin
ATC Vet code	QJ01MA90
Target species	Calves, pigs and dogs
Indication for use	<p>Treatment of infections caused by gram-positive bacteria, gram-negative bacteria and mycoplasmas susceptible to enrofloxacin in calves, pigs and dogs:</p> <p>Calves: <i>E. coli</i>, <i>Haemophilus</i> spp., <i>Pasteurella</i> spp. <i>Mycoplasma bovis</i>.</p> <p>Pigs: <i>Actinobacillus pleuropneumoniae</i>, <i>E. coli</i>, <i>Pasteurella multocida</i>.</p> <p>Dogs: <i>Staphylococcus</i> spp., <i>E. coli</i>, <i>Haemophilus</i> spp., <i>Pasteurella</i> spp., <i>Salmonella</i> spp.</p> <p>Calves: Treatment of respiratory and alimentary tract diseases of bacterial or mycoplasmal origin (pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia) and secondary bacterial infections subsequent to viral conditions (e.g. viral pneumonia).</p> <p>Pigs: Treatment of respiratory and alimentary tract diseases of bacterial origin (pasteurellosis, coli-bacillosis, coli-septicaemia), Postpartum Dysgalactiae Syndrome (PDS), pleuropneumonia (caused by <i>Actinobacillus pleuropneumoniae</i>) and diseases of the respiratory tract (such as those caused by <i>Pasteurella multocida</i> and enzootic pneumonia).</p> <p>Dogs: Treatment of mono or mixed bacterial infections of the respiratory, digestive and urinary tract, skin and wound infections..</p>

## **MODULE 2**

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (<http://www.hma.eu>).

## MODULE 3

### PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	27.01.2014
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	PT

#### I. SCIENTIFIC OVERVIEW

##### ***For public assessment reports for the first authorisation in a range:***

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

## **II. QUALITY ASPECTS**

### **A. Composition**

The product contains enrofloxacin 50 mg and excipients n-butyl alcohol, potassium hydroxide, water for injections.

The container/closure system consists of a cardboard box with one amber Type I vial of 50 ml or 100 ml with a grey bromobutyl rubber stopper and aluminium cap or a cardboard box with one amber Type II vial of 50 ml or 100 ml with a grey bromobutyl rubber stopper and aluminium cap.

The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the presence of preservative is justified.

### **B. Method of Preparation of the Product**

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

### **C. Control of Starting Materials**

The active substance is enrofloxacin, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Two active substance manufacturers are requested. One of them submits the master file according to the Active Substance Master File procedure. The CEP is included according to the European Pharmacopoeia (EDQM) by the other one.

### **D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies**

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

### **E. Control on intermediate products (pharmaceuticals)**

Not applicable.

#### **F. Control Tests on the Finished Product**

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

#### **G. Stability**

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

#### **H. Genetically Modified Organisms**

Not applicable.

#### **J. Other Information**

Not applicable.

### **III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)**

#### **For generics, insert in the relevant sections as appropriate:**

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological, toxicological, user safety and residues tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers.

#### **III.A Safety Testing**

##### **Pharmacological Studies**

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, pharmacological studies are not required.

##### **Toxicological Studies**

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, toxicological studies are not required.

##### **User Safety**

As this is a generic application according to Article 13, and presents identical risks to the user as those of the reference product, no user risk assessment is required. Warnings and precautions as listed on the product literature are the same as for the reference product and are adequate to ensure safety to users of the product.

##### **Ecotoxicity**

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

#### **III.B Residues documentation**

##### **Residue Studies**

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, residue depletion studies are not required.

##### **Withdrawal Periods**

Accordingly, the same withdrawal periods as for the reference product are advised in the SPC and package leaflet:

- Calves: meat and offal: 7 days
- Pigs: meat and offal: 7 days

#### **IV. CLINICAL ASSESSMENT (EFFICACY)**

***For generics, insert in the relevant sections as appropriate:***

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

## **V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT**

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

## **MODULE 4**

### **POST-AUTHORISATION ASSESSMENTS**

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website ([www.hma.eu](http://www.hma.eu)).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None