Austrian
Federal Office for
Safety in Healthcare
BASG

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A

VETERINARY MEDICINAL PRODUCT

Baytril Direct 100 mg/ml Solution for Injection for Pigs
AT/V/0007/001/DC

Since September 2012:

Baytril 1nject 100 mg/ml Solution for Injection for Cattle and Pigs
AT/V/0007/002/DX/001

Date: 29/06/2011
Last update: 25/11/2019

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Baytril Dircect and Baytril 1nject AT/V/0007/001-2/DC
Bayer Austria GmbH

Publicly available assessment report

Modules 1-3 reflect the scientific discussion for the approval of Baytril Direct 100 mg/ml Solution for Injection for pigs. The procedure was finalised on 22/06/2011.

On 20/09/2012 this marketing authorisation has been extended with a second strength: Baytril 1nject 100 mg/ml Solution for Injection for Cattle and Pigs.

For information on changes after this date please refer to module 4.

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	AT/V/0007/001/DC AT/V/0007/002/DX/001
Name, strength and pharmaceutical form	001: Baytril Direct 100 mg/ml Solution for Injection for Pigs 002: Baytril 1nject 100 mg/ml Solution for Injection for Cattle and Pigs
Applicant	Bayer Austria GmbH Herbststrasse 6-10 1160 Vienna Austria
Active substance	Enrofloxacin
ATC Vetcode	QJ01MA90
Target species	AT/V/0007/001/DC: Pigs AT/V/0007/002/DX/001: Cattle and pigs
Indication for use	001 – Baytril Direct: For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as secondary pathogen in pigs. 002 – Baytril 1nject: Cattle: For the treatment of respiratory tract infections caused by enrofloxacin-sensitive *Histophilus somni, Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* spp. For the treatment of Mastitis caused by enrofloxacinsensitive *E. coli*. Pigs: For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and complicated by *Haemophilus parasuis* as secondary pathogen in pigs.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Reference medicinal product	Baytril RSI 100 mg/ml Injektionslösung für Rinder und Schweine
Date of completion of the original decentralised procedure	AT/V/0007/001/DC: 22/06/2011 AT/V/0007/002/DX/001: 20/09/2012
Concerned Member States for original procedure Concerned Member States for RUP 1st waive	AT/V/0007/001/DC: BE, DE, FR, IE, IT, LU, NL, UK AT/V/0007/002/DX/001: DE, FR, IE, IT, UK

I. SCIENTIFIC OVERVIEW

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

II.A Qualitative and quantitative particulars

The product contains 100 mg/ml enrofloxacin as active substance and the excipients arginine, benzyl alcohol, n-butanol and water for injection.

The container/closure system 100 ml brown glass bottle, type I, with chlorobutyl rubber stopper and aluminium crimp cap.

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

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B Method of Preparation of the Product

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

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

II.C Control of Starting Materials

The active substance is enrofloxacin, an established active substance which is 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.

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

II.D Control on intermediate products (pharmaceuticals)

Not applicable.

II.E 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<s> have been provided demonstrating compliance with the specification.

II.F 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.

The claim of stability after broaching is acceptable, for details see section 6.3 of SPC.

II.G Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on safety and residues are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

III.A Safety Testing

Pharmacological Studies

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

Toxicological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, the results of toxicological tests are not required.

User Safety

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, a detailed user safety is not required. The user safety warnings are the same as for the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant provided a Phase I environmental risk assessment (ERA) for enrofloxacin in compliance with the relevant CVMP/VICH guidelines GL6 and GL38. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will be used to treat a small number of animals in a flock herd. The results of the assessment for the terrestrial plants indicate that the initial predicted environmental concentration in soil is less than 100 µg/kg for all categories of the target animal species.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed in the SPC.

III.B Residues documentation

No residue depletion studies were conducted because, in accordance with the data requirements of the applicable European bioequivalence guideline, it was demonstrated that the product is a generic of Baytril RSI 100 mg/ml solution for injection and that the residue depletion profile will be the same.

MRLs

Maximum Residuee Limits (MRLs) for the active substance enrofloxacin is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. The marker substance is the sum of enrofloxacin and ciprofloxacin.

Table 1: MRLs are listed below:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Bovine, ovine, caprine	100 100 300 200 100	Muscle Fat Liver Kidney Milk
		Porcine, rabbit	100 100 200 300	Muscle Fat Liver Kidney

The excipients arginine, benzyl alcohol and n-butanol which are contained in the generic product are included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as “No MRL required”. The excipient water for injection is “Out of Scope” of that Regulation.

Withdrawal Periods

The withdrawal periods for the proposed product are the same as those of the reference product as follows:

Cattle:
Meat and offal: s.c.: 14 days
i.v.: 7 days
Milk: s.c.: 120 hours
i.v.: 72 hours

Pigs:
Meat and offal: i.m.: 12 days

IV. CLINICAL ASSESSMENT (EFFICACY)

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.
The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, pharmacodynamics and pharmacokinetic studies are not required.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, tolerance studies are not required.

IV.B Clinical Studies

Laboratory Trials

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, laboratory studies are not required as they have already been presented for the reference product.

Field Trials

As this is a generic application according to Article 13(1), and bioequivalence with the reference product has been demonstrated, field studies are not required as they have already been presented for the reference product.

The product is efficacious when used according to the SPC.

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 Heads of Veterinary Medicines Agencies website (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.

Summary of change (Application number)	**Approval date**
Line Extension (AT/V0007/002/DX/001)	20/09/2012
This marketing authorisation Baytril Direct was renewed unlimited. (AT/V/0007/001/R/001)	25/05/2016
This marketing authorisation Baytril 1nject was renewed unlimited. (AT/V/0007/002/R/001)	28/06/2018
No further significant changes until today.	26/11/2019