IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Bimoxyvet LA 150 mg/ml, Suspension for Injection for cattle, sheep and pigs

PRODUCT SUMMARY

EU Procedure number	IE/V/0362/001
Name, strength and pharmaceutical form	Bimoxyvet LA 150 mg/ml, Suspension for Injection for cattle, sheep and pigs
Active substances(s)	Amoxicillin
Applicant	Laboratorios Maymó, S.A. Via Augusta 302 08017 Barcelona Spain
Legal basis of application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Date of Authorisation	21 December 2016
Target species	Cattle, Pigs, Sheep
Indication for use	In cattle: Treatment of respiratory and other infections caused by amoxicillin susceptible Gram-positive and Gram-negative bacteria. In sheep and pigs: Treatment of infectious diseases caused by or associated with amoxicillin susceptible bacteria.
ATCvet code	QJ01CA04
Concerned Member States	AT, BE, DK, FI, FR, IT, PL, PT, RO and ES

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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. Possible reactions that may be observed following administration of the product 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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

The product contains 150 mg/ml of the active substance amoxicillin, as amoxicillin trihydrate, and the excipients aluminium di-tri stearate, glycerol monocaprylate Type I and propylene glycol dicaprylocaprate.

The container/closure system is 100 ml and 250 ml clear Type I glass vials sealed with a bromobutyl rubber stopper and an aluminium overseal.

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

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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

C.Control of Starting Materials

The active substance is amoxicillin trihydrate, an established 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 has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D.Control on Intermediate Products

Not applicable.

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

F.Stability

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

G.Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III SAFETY AND RESIDUES ASSESSMENT

The product is a suspension for injection containing 150 mg/ml of the active substance amoxicillin, as amoxicillin trihydrate.The legal basis for the application is in accordance with Article 13.1 of Directive 2001/82/EC, as amended (a generic application).

The reference product cited is Bimoxyl LA 150 mg/ml Suspension for Injection (Bimeda Chemicals Limited; VPA 10126/009/001) which was first authorised in the RMS (Ireland) on 01/10/1987 in accordance with a full application dossier and for which the marketing authorisation remains valid.

It was confirmed that both the formulation and manufacturing process in respect of the candidate product are identical to those of the reference product (Bimoxyl LA 150 mg/ml). Consequently, bioequivalence between candidate and reference formulations could be accepted and *in-vivo* bioequivalence studies were not required.

The safety and efficacy aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are in line with those of the reference product and other similar products and are adequate to ensure safety of the product to users, the environment and consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application and bioequivalence with a reference product was demonstrated, results of pharmacological studies were not required.

Toxicological Studies

As this is a generic application and bioequivalence with a reference product was demonstrated, results of toxicological studies were not required.

User Safety

A user safety assessment was provided. The candidate formulation will be handled, stored, administered to the same target species, using the same posologies and routes of administration and disposed of in the same manner as for the reference product. Consequently, no difference in potential risk to the user is considered to arise between the candidate and reference product formulations.

The primary risk posed to the user is that of hypersensitivity-type reactions. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

An environmental impact assessment was provided.

Phase I
A Phase II ERA was required as the Phase I assessment showed that the highest PECsoil initial value (determined for weaner pigs) exceeded the trigger value for a phase II assessment.

Phase II Tier A
A Phase II Tier A assessment was conducted.

Based upon the data provided, the product will not present an unacceptable risk for the environment and a Tier B assessment was not necessary.

Conclusion
Based on the data provided, the product is not expected to pose an unacceptable risk for the environment when handled, administered, stored and disposed of in accordance with the recommendations included in the SPC.

III.B Residues Documentation

Residue Studies

As the candidate formulation is qualitatively and quantitatively identical to that of the reference product and is to be administered to the same target species, using the same route of administration and the same posology as already approved for the reference product, studies investigating the depletion of residues from the injection site were not required.

MRLs

Amoxicillin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissue
Amoxicillin	Amoxicillin	All food producing species	50 microgram/kg 50 microgram/kg 50 microgram/kg 50 microgram/kg 4 microgram/kg	Muscle Fat Liver Kidney Milk

All excipients are either included in Table I of Commission Regulation (EU) No 37/2010, or are not considered to be pharmacologically inactive at the proposed inclusion rates.

Withdrawal Periods

As the candidate formulation is qualitatively and quantitatively identical to that of the reference product and is to be administered to the same food-producing target species, using the same route of administration (IM) and the same posology as already approved for the reference product, it was accepted that the same withdrawal periods could be applied to the candidate formulation as already approved for the reference product, namely;

Cattle: Meat and offal:18 days.
Milk: 72 hours.

Sheep: Meat and offal: 21 days.
Not authorised for use in sheep producing milk for human consumption.

Pigs:Meat and offal: 21 days.

The withdrawal periods are deemed adequate to ensure consumer safety.

IV. CLINICAL ASSESSMENT

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13.1, 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.

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application and bioequivalence with a reference product was demonstrated, results of pharmacological studies were not required.

Tolerance in the Target Species of Animals

As the candidate formulation is qualitatively and quantitatively identical to that of the reference product and is to be administered to the same target species, using the same route of administration (IM) and the same posology as already approved for the reference product, no difference between candidate and reference product in terms of target animal tolerance is expected. Consequently, no target animal tolerance study data was required.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

As the candidate formulation is qualitatively and quantitatively identical to that of the reference product and is to be administered to the same target species, using the same route of administration (IM) and the same posology as already approved for the reference product, the risk for the development of bacterial resistance to amoxicillin in the candidate formulation is not expected to differ from that of the reference product.

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Field Trials

As this is a generic application according to Article 13.1, and bioequivalence with a reference product has been demonstrated, field trials 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 benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.

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.

Changes:
None.