IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

VitaBim B1 100 mg/ml Solution for Injection for Cattle and Sheep

PRODUCT SUMMARY

EU Procedure number	IE/V/0551/001/DC
Name, strength and pharmaceutical form	VitaBim B1 100 mg/ml Solution for Injection for Cattle and Sheep
Active substance(s)	Thiamine hydrochloride
Applicant	Bimeda Animal Health Limited 2, 3 & 4 Airton Close, Airton Road, Tallaght, Dublin 24, Ireland
Legal basis of application	Generic application in accordance with Article 18 of Directive 2001/82/EC as amended.
Date of completion of procedure	27 November 2024
Target species	Cattle and sheep
Indication for use	For the treatment of cerebrocortical necrosis in cattle and sheep and as an adjunct in metabolic disorders of cattle.
ATCvet code	QA11DAO1
Concerned Member States	BE, DK, IT, ES, PL, SE
Withdrawn CMS during original decentralised procedure	FR

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (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 relevant articles of Regulation (EU) 2019/6. 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.
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

Each ml of product contains the active substance thiamine hydrochloride 100 mg and the excipients benzyl alcohol, sodium hydroxide, hydrochloric acid, concentrated, disodium edetate, and water for injections. The container/closure system consists of a type I amber glass vial with a red bromobutyl rubber stopper and a plain aluminium overseal.
The choice of the formulation is justified. 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 thiamine hydrochloride is an established active substance. 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 the specification has been provided.
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
The active substance is fully tested to ensure compliance with the specification immediately prior to use in manufacture of the product.
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.A Safety Testing

Pharmacological Studies
As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of pharmacodynamic or pharmacokinetic tests are not required.

Toxicological Studies
As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

User Safety
The applicant has provided a user safety assessment in compliance with the relevant guideline.
The product contains the same concentrations of the active substance and excipients as the reference veterinary medicinal product. In addition, the product is intended to be administered by the same route of administration at the same dose and for the same indications for use in the same species as the reference product. Given no qualitative or quantitative difference in terms of active substance and excipients, no greater risk to the user is anticipated following use of the product than that which already exists 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

Phase I
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the product contains thiamine hydrochloride (Vitamin B1) as its active pharmaceutical ingredient, which is a natural substance widely found in plants such as cereals and pulses. Given that the product will, in the majority of cases only be used on a small group of animals, the authorised period of use is very short and the active substance is rapidly metabolised in the treated animals it can be concluded that use of the product will not alter the concentration or distribution of thiamine in the environment.

Conclusion

Based on the information provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted as the product and reference product have the same qualitative and quantitative composition in terms of active substance and excipients. The CVMP Guideline on determination of withdrawal periods for edible tissues (EMA/CVMP/SWP/735325/2012 Rev.2) provides the following guidance for generic products:
"When the formulation (active and inactive ingredients), the dose schedule, the route(s) of administration and the target species of a specific generic product, are identical to a currently approved product (i.e. the reference product), or it has been adequately justified that any differences in formulation are so minor such that they will not impact on residue depletion, then the withdrawal period of the latter can be used for the former."
The product is intended to be administered by the same route of administration (by intramuscular or slow intravenous injection), at the same dose, and for the same indications for use in the same species as the reference product. It is accepted that the formulations are qualitatively and quantitatively the same and that residue depletion studies are not required.

MRLs
Vitamin B1 (thiamine hydrochloride) 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 (µg/kg)	Target tissue	Other provisions
Vitamin B1	Not applicable	All food-producing species	No MRL required	Not applicable	NO ENTRY

Withdrawal Periods

Based on the data provided, the following withdrawal periods are justified:
Meat and offal: Zero days.
Milk: Zero days.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been demonstrated, pre-clinical studies are not required.
The efficacy claims for this product are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

No target animal tolerance data specific to the candidate product have been presented, however, given the legal basis of the application and the similarity of formulations, it was accepted that the candidate product will not present any greater risk to the target animal than that posed by the reference product. The omission of product-specific target animal tolerance study data was therefore accepted.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been demonstrated, clinical 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 risk benefit 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 in the Union Product Database (UPD).
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.