MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE MEDICAMENTOS VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Imidokal 85 mg/ml solution for injection for dogs and cattle

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PRODUCT SUMMARY

EU procedure number	ES/V/0422/001/DC
Name, strength and pharmaceutical form	Imidokal 85 mg/ml solution for injection
Applicant	Vet-Agro Multi-Trade Company Sp. z o.o. Gliniana 32 20-616 Lublin, Poland
Active substance(s)	Imidocarb
ATC vetcode	QP51EX01
Target species	Dogs and cattle
Indication for use	Dogs: Treatment of piroplasmosis caused by Babesia canis, B. gibsoni and B. vogelli. Cattle: Treatment and prevention of piroplasmosis caused by Babesia argentina, B. bigemina, B. bovis and B. divergens. Treatment of anaplasmosis caused by Anaplasma marginale

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP)	IMIZOL
Marketing authorisation holder	Merck Sharp & Dohme Animal Health, S.L
MS where the RP is or has been authorised	Spain
Marketing authorisation number EU procedure number	205 ESP
Date of authorisation	11/12/1991
Date of completion of the original decentralised procedure	28/06/2023
Concerned Member States for original procedure	IE, IT, PT
Withdrawn CMS during original decentralised procedure	-

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product Imidokal 85 mg/ml solution for injection for cattle and dogs is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

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

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

2.A. Product description

The VMP contains 85 mg/ml imidocarb (as 121.15 mg/ml imidocarb dipropionate) as active substance. Other ingredients are propionic acid and water for injection.

The container/closure system is colourless polypropylene plastic bottle (20 and 50 ml) closed with bromobutyl rubber stopper type I and aluminium cap with plastic lid.

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

2.B. Description of the manufacturing method

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

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

2.C. Production and control of starting materials

The active substance is Imidocarb dipropionate, an established substance not described in the European Pharmacopeia/National pharmacopeia of a member state/pharmacopeia of a third country. 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 VMP.

2.D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable

2.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 VMP.

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.

2.F. Stability tests

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 VMP throughout its shelf life when stored under the approved conditions.

2.G. Other information

Not applicable

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. Safety tests

Pharmacological studies

As this is a generic application according to Article 18, and bioequivalence with the reference product has been demonstrated, results of pharmacological tests are not required.

Toxicological studies

As this is a generic application according to Article 18, and bioequivalence with the reference product has been demonstrated, results of toxicological tests are not required.

User safety

The applicant has provided a brief user safety assessment in compliance with the relevant guideline, which shows that the candidate product has the same composition in active substances and excipients than the reference product, it is assumed that the risks for the user will be similar to those associated with the use of the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

In accordance with article 18(7) of the Regulation 2019/6 and the CVMP Reflection Paper on the interpretation of the mentioned article, the applicant has proven that there is at least one VMP authorised in the EU after 2005 (i.e Hemocarb, PuAR included in the dossier). Hemocarb was authorised in ES in 2019 and lead to the same environmental exposure as Imidokal (same dose, indications, target species). In consequence, the conditions set in the above mentioned RP for not providing an ERA are fulfilled.

In addition, considering the Product Information, the use of this product leads to a PECsoil-initial under the regulatory threshold that required a phase II assessment. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentration in soil is less than 100 µg/kg. No unacceptable risks for the environment are expected when the product is used, handled and disposed according to the information included in the SPC.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted because this is a generic application according to Article 18, and bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

Imidocarb is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal Species**	**MRL**	**Target tissues**	**Other provision**	**Therapeutic Classification**
Imidocarb	Imidocarb	Bovine	300 µg/kg 2000 µg/kg 50 µg/kg 1500 µg/kg 50 µg/kg	Muscle Liver Fat Kidney Milk		QP51EX01 Imidocarb
		Ovine	300 µg/kg 2000 µg/kg 50 µg/kg 1500 µg/kg	Muscle Liver Fat Kidney	Not for use in sheep from consumption which milk is produced for human	

Withdrawal Periods

The same withdrawal periods than the reference product are proposed:

Cattle
Meat and offal: 213 days.
Milk: 6 days

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

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

4.A. Pre-Clinical Studies

No pre-clinical studies were performed.

Pharmacology

As details on pharmacodynamics and pharmacokinetics have been sufficiently described in the file of the reference product, no further documentation is needed.

Development of resistance and related risk in animals

Adequate warnings and precautions appear on the product literature.

Dose determination and confirmation

This is a Generic application (Art 18 of Regulation 2019/6). The bioequivalence with the reference product can be assumed. Therefore, the reference is made to the originator dossier and the same dosage as per the reference product applies for the candidate product.

Tolerance in the target species of animals

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

4.B. Clinical trials

This is a Generic application (Art 18 of Regulation 2019/6). The bioequivalence with the reference product has been demonstrated. Therefore, no clinical data have been submitted. The efficacy claims for this product are equivalent to those of the reference product.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. 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 VMP.

None.