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French agency for veterinary medicinal products

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

PRODUCT SUMMARY

EU procedure number	FR/V/0466/001/DC
Name, strength and pharmaceutical form	Imidotyl 85 mg/ml solution for injection for cattle and dogs
Applicant	Vet-Agro Multi-Trade Company Sp. z o.o.
Active substance(s)	Imidocarb
ATC vetcode	QP51EX01
Target species	Cattle, dogs.
Indication for use	Cattle: - Treatment and prophylaxis of babesiosis caused by *Babesia divergens*, *B. bigemina* and *B. bovis*. - Treatment of anaplasmosis caused by *Anaplasma marginale* and mixed infections by those *Babesia species* and *A. marginale*. For prophylaxis, see also section “3.4. Special warnings”. Dogs: - Treatment and prophylaxis of babesiosis caused by *Babesia canis* and *B. vogelli*.

Imidotyl 85 mg/ml solution for injection for cattle and dogs	FR/V/0466/001/DC
	DCP
Publicly available assessment report	

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 (EC) 2019/6.
Reference product (RP)	CARBESIA
Marketing authorisation holder	Intervet
MS where the RP is or has been authorised	France
Marketing authorisation number EU procedure number	FR/V/6280218 7/1980
Date of authorisation	22/12/1980
Date of completion of the original decentralised procedure	26/07/2023
Concerned Member States for original procedure	BE, EL, HR, HU, NL, PL and RO

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product Imidotyl 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 slight 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)

A. Product description

The VMP contains 85 mg of imidocarb (as imidocarb dipropionate) as the active substance and the excipients propionic acid and water for injections.

The container/closure system is a bottle of 20 and 50 ml, closed with rubber stopper.

The choice of the formulation is justified.

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

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.

C. Production and control of starting materials

The active substance is imidocarb dipropionate, 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 this specification have been provided.

Scientific data have been provided and 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 tests carried out on isolated intermediates during the manufacturing process

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 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.

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.

G. <Other information>

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

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

The toxicological/safety aspects of this VMP is/are identical to the reference VMP.
Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to users / the environment / consumers. Some specific warnings are included in regards of the risk to the environment.

A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety of the users.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required.

B. Residues documentation

Residue tests

The applicant has not submitted residues data on the basis that bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

The active substance imidocarb is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010, as follows

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions	Regulation
Imidocarb	Imidocarb	Bovine	300 µg/kg 50 µg/kg 2000 µg/kg 1500 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	No entry	37/2010 of 22.12.2009
		Ovine	300 µg/kg 50 µg/kg 2000 µg/kg 1500 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption	

The composition of the product IMIDOTYL121.15 MG/ML SOLUTION FOR INJECTION FOR DOGS AND CATTLE is acceptable according to the European Regulation (EC) No 470/2009.

Withdrawal Periods

Given that bioequivalence with the reference product, CARBESIA, is satisfactory documented, the same withdrawal periods approved for the reference product was proposed to be applied to the candidate product IMIDOTYL 121, 15 MG/ML SOLUTION FOR INJECTION FOR DOGS AND CATTLE.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

IMIDOTYL 121.15 MG/ML SOLUTION FOR INJECTION FOR DOGS AND CATTLE is solution for injection containing imidocarb. This product is indicated for

treatment and prevention of babebiosis in dogs;
treatment and prevention of babesiosis in cattle;
treatment of anaplasmosis in cattle.
treatment of mixed infections in cattle.

This application is for a generic product, submitted in accordance with Article 18 of Regulation (EU) No. 2019/6, using the decentralised procedure. The reference product is CARBESIA, marketed by INTERVET which has been authorised in the France since 22/12/1980.

A. Pre-Clinical Studies

Pharmaceutical form

The test and the reference products have the same pharmaceutical form: solution for injection.

Active substance qualitative and quantitative composition

The test and reference products have the same qualitative and quantitative composition in active substance: 85 mg of imidocarb (*i.e*. 121.15 mg of imidocarb dipropionate) per mL of product.

Bioequivalence studies

The bioequivalence between the test and reference product is satisfactory demonstrated according to the point 7.1 of the GL EMA/CVMP/016/2000-Rev.4*.

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

The bibliography is provided to verify the resistance of target pathogens against imidocarb.

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

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference product has been demonstrated, results of target animal safety studies are not required.

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.