Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

ISOFLUTEK 1000 mg/g inhalation vapour, liquid [BE, CZ, DE, ES, HU, LU, NL, PT, RO]
ISOTEK 1000 mg/g inhalation vapour, liquid [PL]

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0261/001/ DC
Name, strength and pharmaceutical form	ISOFLUTEK 1000 mg/g inhalation vapour, liquid [BE, CZ, DE, ES, HU, LU, NL, PT, RO] ISOTEK 1000 mg/g inhalation vapour, liquid [PL]
Applicant	Laboratorios KARIZOO, S.A. Pol. Ind. La Borda, Mas Pujades 11-12 CALDES DE MONTBUI. 08140.
Active substance(s)	Isoflurane
ATC Vet code	QN01AB06
Target species	Horses, dogs, cats, ornamental birds, reptiles, rats, mice, hamsters, chinchillas, gerbils, guinea pigs and ferrets.
Indication for use	Induction and maintenance of general anaesthesia.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	25/01/2017
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	BE, CZ, DE, ES, HU, LU, NL, PL,PT, RO]

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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

For applications based on informed consent to another authorisation:

The quality / safety / efficacy aspects of this product is/are identical to original product. The initial application for Isoflo was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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II. QUALITY ASPECTS

A. Composition

The product contains 1000 mg/g of isoflurane. There is no excipient.

The container/closure system is an amber coloured glass bottle (Type III) containing 250 ml isoflurane. The bottle has a polypropylene/polyethylene roll-on pilfer-proof cap and a high density polyethylene neck collar with wing ("keyed" collar), which is fitted over the cap and bottle neck.
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.

B. Method of Preparation of the Product

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

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

C. Control of Starting Materials

The active substance is isoflurane, an established active substance 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 have been provided.

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

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

F. 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 have been provided demonstrating compliance with the specification.

G. Stability

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.

H. Genetically Modified Organisms

J. Other Information

III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13.1 - Generic application of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

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

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and the consumers.

III.A Safety Testing

Pharmacological Studies

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

Toxicological Studies

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

User Safety

Despite not having provided a user risk assessment, it can be accepted that the proposed formulation will not present any greater risk to the user than that posed by the reference product.

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the treatment with the product does not cause environmental damage when used in accordance with the proposed SPC.

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

III.B Residues documentation
(Delete for non food producing species and for immunologicals)

Residue Studies

As this application is in accordance with Article 13 (1) - Generic application of Directive 2001/82/EC, the applicant shall not be required to provide the results of residues tests because all these data are in the documentation that supports the marketing authorization of the reference product.

MRLs

Isoflurane is listed in table 1 of the Comission Regulation (EU) No 37/2010 for equidae with no MRL required.

MRLs are listed below:

Pharmacologically active substance	Animal species	Other provisions
Isoflurane	Equidae	For use as anaesthetic only

Withdrawal Periods

The applicant proposes the same withdrawal time as approved for the reference product. As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, a withdrawal period of 2 days for meat in horses is justified and this is adequate to ensure consumer safety.

Horses (Meat and offal): 2 days

IV. CLINICAL ASSESSMENT (EFFICACY)

For generics, insert in the relevant sections as appropriate:

As this is a generic application according to Article 13, 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.

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.