Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Sevotek 1000 mg/g inhalation vapour, liquid for dogs

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0278/001/ DC
Name, strength and pharmaceutical form	Sevotek 1000 mg/g inhalation vapour, liquid
Applicant	LABORATORIOS KARIZOO, S.A.
Active substance(s)	Sevoflurane
ATC Vet code	ATCvet code: QN01AB08
Target species	Dogs
Indication for use	For the induction and maintenance of 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 decentralised procedure	20/12/2017
Date product first authorised in the Reference Member State (MRP only)	----------
Concerned Member States for original procedure	BE, CZ, DK, LU, FR, DE, HU, NL, PO, PT, RO, SK, SE, UK

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 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.

II. QUALITY ASPECTS

A. Composition

The product contains 1000 mg/g of sevoflurane. There are no excipients

The container/closure system is an amber coloured glass bottle (Type III) closed with a polypropylene/polyethylene 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 sevoflurane, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practices.

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. The suitability of the active substance used in the manufacture of the medicinal product is demonstrated by the use of Certificate of Conformity of Ph. Eur.

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

Scientific data and/or certificates of suitability issued by the EDQM 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.

E. Control on intermediate products (pharmaceuticals)

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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<s> have been provided demonstrating compliance with the specification.

G. Stability

Stability data on the active substance is in accordance with applicable European guidelines.

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 (PHARMACOTOXICOLOGICAL) (*for pharmaceuticals only)*

As this is a generic application according to Article 13- 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 and the environment.

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 pose a greater risk to the user than 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.

IV. CLINICAL ASSESSMENT (EFFICACY)

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.

MODULE 4

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 veterinary Heads of Agencies website (www.hma.eu).

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.

4.8 Interaction with other medicinal products and other forms of interaction

The use of sevoflurane with nondepolarising muscle relaxants has not been evaluated in dogs.
In cats sevoflurane has been shown to exert some neuromuscular blocking effect, but this is only apparent at high doses. In humans sevoflurane increases both the intensity and duration of neuromuscular blockade induced by nondepolarising muscle relaxants. Neuromuscular blocking agents have been used in cats anaesthetised with sevoflurane without any unexpected effects.

4.9 Amounts to be administered and administration route Induction of anaesthesia:

For mask induction using sevoflurane, inspired concentrations of 5 to 7% sevoflurane with oxygen are employed to induce surgical anaesthesia in the healthy dog, and 6 to 8% sevoflurane with oxygen in the cat. These concentrations can be expected to produce surgical anaesthesia within 3 to 14 minutes in dogs and within 2 to 3 minutes in cats. Sevoflurane concentration for induction may be set initially, or may be achieved gradually over the course of 1 to 2 minutes. The use of premedicants does not affect the concentration of sevoflurane required for induction.

In the cat surgical anaesthesia is maintained with sevoflurane concentrations of 3.7-4.58%.

5.1 Pharmacodynamic properties

The MAC in cats 3.1%.

Sevoflurane in the cat did not increase intracranial pressure during normocapnia.
In cats no effect of sevoflurane on spleen size were recorded.
The pharmacokinetics of sevoflurane have not been investigated in the cat. However, based on sevoflurane blood solubility comparisons, feline uptake and elimination kinetics of sevoflurane are expected to be similar to those in the dog. Clinical data for the cat indicate rapid onset of, and recovery from, sevoflurane anaesthesia.

Safety/efficacy changes

Summary of	Section updated in	Approval date
(Type; application number)	**Module 3**	
Addition of target species - cats ES/V/0278/001/IB/001	SPC and PIL texts	14/05/2018