DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Uristop 40 mg/ml syrup for dogs

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PRODUCT SUMMARY

EU procedure number	ES/V/0288/001/MR
Name, strength and pharmaceutical form	Uristop 40 mg/ml syrup for dogs
Applicant	Laboratorios Karizoo S.A. Carrer Mas Den Pujades 11-12, Poligono Industrial La Borda 08140 Caldes De Montbui (Barcelona). Spain
Active substance(s)	Phenylpropanolamine
ATC vetcode	QG04BX91
Target species	Dogs
Indication for use	Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch. Efficacy has been only demonstrated with ovariohysterectomised bitches.

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)	Propalin Syrup 40 mg/ml Dogs
Marketing authorisation holder	Vetoquinol UK Ltd
MS where the RP is or has been authorised	United Kingdom
Marketing authorisation number	08007/4035
EU procedure number	-
Date of authorisation	27/01/1993
Date of completion of the original mutual recognition	Day 90: 08/05/2024
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	03/03/2014
Concerned Member States for original procedure	AT, BE, CZ, DE, EE, FR, IT, LT, LV, NL, PL, PT, RO, SK, UK(NI)
Withdrawn CMS during original mutual recognition procedure	-

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) 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 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 is a syrup that contains phenylpropanolamine hydrochloride, as the active substance and sorbitol as the excipient.

The container system are 50 and 100 ml bottles of high density polyethylene, with a syringe adaptor of low density polyethylene and child resistant screw cap of polypropylene and polyethylene.

The choice of the formulation is justified.

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 phenylpropanolamine hydrochloride, an established substance described in the European Pharmacopeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The information on the active substance is provided by ASMF.

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.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

2.D. Control tests 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 sites 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.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated, results of safety tests are not required.

The safety aspects of this VMP is identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the VMP to users.

3.A. Safety tests

User safety

The applicant provided a user safety assessment in compliance with the relevant guideline which showed that no new risks were identified compared to the reference product.

The same user safety warnings approved for the reference product were proposed to be applied to the VMP.

Additionally, as hypersensitivity reactions due to the presence of active substance phenylpropanolamine hydrochloride cannot be excluded, the user should be warned and the hazard should be specified.

Finally, the measures to protect children from accidental ingestion have been strengthened.

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

Environmental Risk Assessment

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

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.

3.B. Residues documentation

NA

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to 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.

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.