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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28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vetipracin 250 000 IU/g powder for use in drinking water/milk

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PRODUCT SUMMARY

EU procedure number	ES/V/0442/001/DC
Name, strength and pharmaceutical form	Vetipracin 250 000 IU/g powder for use in drinking water/milk
Applicant	Laboratorios Maymó, S.A.U. Via Augusta 302 Barcelona 08017 Spain
Active substance(s)	Apramycin sulfate
ATC vetcode	QA07AA92
Target species	Pig (weaned piglet), cattle (pre-ruminant), chicken (broiler) and rabbit
Indication for use	Pig (weaned piglet): Treatment of bacterial enteritis caused by *Escherichia coli* susceptible to apramycin. Cattle (pre-ruminant): Treatment of bacterial enteritis caused by *Escherichia coli* and clinical outbreaks due to *Salmonella enterica* subsp. enterica serovar Dublin (Salmonella Dublin) susceptible to apramycin. Treatment should be based on prior confirmation of the Salmonella serovars involved or at least the availability of epidemiological data confirming the presence of this serovar. Chicken (broiler): Treatment of colibacillosis caused by *Escherichia coli* susceptible to apramycin. Rabbit: Treatment and metaphylaxis of bacterial enteritis caused by *Escherichia coli* susceptible to apramycin. The presence of the disease in the herd must be established before the product is used.

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*	Hybrid application in accordance with Article 19(1) of Regulation (EU) 2019/6.
Reference product (RP)	Girolan polvo para administración en agua de bebida o en lactorremplazante para porcino, bovino (terneros), pollos y conejos
Marketing authorisation holder	Elanco GmbH
MS where the RP is or has been authorised	Spain
Marketing authorisation number	379 ESP
EU procedure number	-
Date of authorisation	28/05/1992
Date of completion of the original decentralised procedure	Day 210: 05/03/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	BG, DK, FR, PT
Withdrawn CMS during original decentralised 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, 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 250000 IU/g of apramycin sulfate and lactose monohydrate as excipient.

The container/closure system is a bag composed of a triple complex film formed by a polyester film, an aluminium film and a sheet of low density polyethylene united by a polyurethane-based adhesive.

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 apramycin sulfate, is not described in Ph. Eur., but a monograph is included in the British Pharmacopoeia. The information on the active substances is provided by presenting an ASMF. 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.

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 (18 months) when stored under the approved conditions.

2.G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of pharmacological or toxicological tests are not required.

3.A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that the risk mitigation measures as approved for the reference product are also appropriate for this hybrid product.

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

Environmental Risk Assessment

The application for marketing authorisation of Vetipracin 250000 IU/g powder for use in drinking water/milk is exempt from submitting an Environmental Risk Assessment (ERA) according to Article 18(7) of Regulation (EU) 2019/6 as an ERA has already been performed for the same active substance and exposure level in the EU in accordance with VICH GL38 (“Guideline on environmental impact assessment for veterinary medicinal products - Phase II” [CVMP/VICH/790/03-FINAL]). Therefore, as there are similar products already authorized in the EU after October 2005 (EMA/CVMP/ERA/622045/2020), a complete data package for environmental risk assessment is not

required. No unacceptable environmental risk is expected when the product is used, handled and disposed according to the information included in the SPC.

3.B. Residues documentation

Residue tests

Given that this veterinary medicinal product has the same pharmaceutical form, is intended to be used in the same species, at the same dose and treatment regimen as the reference product and bioequivalence has been demonstrated, no residue depletion studies have been conducted.

Maximum Residue Limits

Apramycin is included 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
Apramycin	Apramycin	Bovine	1000 µg/kg 1000 µg/kg 10000 µg/kg 20000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
	NOT APPLICABLE	Ovine Porcine Chicken Rabbit	No MRL required.	NOT APPLICABLE	For oral use only. Not for use in animals from which milk or eggs are produced for human consumption.

The excipient Lactose monohydrate listed in section 2. of the SPC is considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Pig:

Meat and offal: Zero days.

Cattle:

Meat and offal: 28 days.

Chicken:

Meat and offal: Zero days.

Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 4 weeks before the start of the laying period.

Rabbit:

Meat and offal: Zero days.

4. EFFICACY DOCUMENTATION

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required.
Information on resistances was provided.
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

None.