DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Albendis 100 mg/ml oral suspension for cattle and sheep

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PRODUCT SUMMARY

EU procedure number	ES/V/0431/001/DC
Name, strength and pharmaceutical form	Albendis 100 mg/ml oral suspension for cattle and sheep
Applicant	Industrial Veterinaria S.A. Esmeralda 19 08950 Esplugues De Llobregat (Barcelona) Spain
Active substance(s)	Albendazole
ATC vetcode	QP52AC11
Target species	Cattle and sheep.
Indication for use	For the treatment of infections caused by gastrointestinal roundworms and tapeworms, lungworms and adult liver flukes in cattle and sheep. Cattle: Gastrointestinal roundworms: Ostertagia Ostertagi, inhibited larval stages of Ostertagia spp., Haemonchus contortus, Cooperia spp., Nematodirus spp., Oesophagostomum radiatum, Bunostomum phlebotomum, Strongyloides papellosus, Trichuris spp. Tapeworms: Moniezia spp. Lungworms: Dictyocaulus spp. Adult liver flukes: Fasciola spp., Fascioloides spp. Sheep: Gastrointestinal roundworms: Ostertagia spp., Haemonchus contortus, Nematodirus spp., Chabertia ovina, Gaigeria spp., Oesophagostomum spp., Bunostomum spp., Trichostrongylus spp. Tapeworms: Moniezia spp. Lungworms: Dictyocaulus spp., Muellerius spp., Protostrongylus spp. Adult liver flukes: Fasciola spp., Fascioloides spp., Dicrocoelium spp.

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.
Reference product (RP)	Valbazen 100 mg/ml sospensione per uso orale per bovini ed ovini
Marketing authorisation holder	Zoetis Italia S.r.l.
MS where the RP is or has been authorised	Italy
Marketing authorisation number	101439065 (1 l); 101439040 (2.5 l)
EU procedure number	-
Date of authorisation	December 1989
Date of completion of the original decentralised procedure	Day 210: 26/02/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, CY, CZ, DE, EE, EL, FR, HR, HU, IT, LT, LV, PL, PT, RO, SI, SK
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 100 mg/ml of albendazole as active substance and sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate, hydroxyethylcellulose, polysorbate 80, propylene glycol, aluminium magnesium silicate, sodium citrate, citric acid monohydrate, simethicone emulsion and purified water as excipients.

The container/closure system is a high-density polyethylene bottles of 1L or 5L that are heat-sealed with a polyethylene (PE) foil and are closed with a screw cap made of HDPE

The choice of the presence of preservatives are justified.

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.

The VMP is manufactured in accordance with the European Pharmacopoeia (Ph. Eur.) and relevant European guidelines.

2.C. Production and control of starting materials

The active substance is albendazole an established substance described in the European Pharmacopeia. 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 and 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.

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 when stored under the approved conditions.

The claim of 2 years stability after first opening is based on the demonstration of stability for a batch opened and stored.

2.G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. Safety tests

Pharmacological studies

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

Bioequivalence studies in cattle and sheep between the candidate formulation and the reference product *Valbazen 100 mg/ml sospensione per uso orale per bovini ed ovini* (Zoetis Italia S.r.l.) have been provided and bioequivalence has been demonstrated.

Toxicological studies

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

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the most likely routes of accidental contact with the product are dermal and ocular exposure.

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 ALBENDAZOLE 100 mg/ml ORAL SUSPENSION 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. Based on the information given in the SPCs of comparable products, a risk to the aquatic and terrestrial environment cannot be excluded. Therefore, suitable risk mitigation measures and/or advice were included in the SPC for this product in line with the SPCs of comparable products.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted on the basis that bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

The active substance, albendazole, is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal Species**	**MRL**	**Target tissues**	**Other provision**	**Therapeutic Classification**
Albendazole	Sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	All ruminants	100 µg/kg 100 µg/kg 1000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/ Agents against endoparasites

Withdrawal Periods

Based on the data provided above, a withdrawal period of 7 days for meat and offal and 84 hours for milk in cattle, and a withdrawal period of 4 days for meat and offal and 96 hours for milk in sheep, are justified.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with 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

None.