ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Albenil 2.5% mg/ml SC Oral Suspension

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Albenil 2.5% mg/ml SC Oral Suspension
Applicant	Virbac Ltd
Active substance(s)	Albendazole
ATC Vetcode	QP52AC11
Target species	Cattle, sheep
Indication for use	A broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs. In **cattle** it is active against the following species: **Roundworms**: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus, Oesophagostomum, Bunostomum, Cooperia,* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia,* **Lungworms**: *Dictyocaulus viviparus,* **Tapeworms**: *Moniezia* spp., **Adult liver fluke**: *Fasciola hepatica*. In **sheep** it is active against benzimidazole-susceptible strains of the following species: **Roundworms:** *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus* (including *N. battus*), *Chabertia* and *Oesophagostomum* It is usually effective against inhibited larvae of *Ostertagia,* **Lungworms:** *Dictyocaulus filaria,* **Tapeworms:** *Moniezia* spp., **Adult liver fluke**: *Fasciola hepatica*. The product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination. The product also contains selenium and cobalt as nutritional supplements.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Albex 2.5% w/v SC Oral Suspension. The initial application for Albex 2.5% w/v SC Oral Suspension was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. 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 benefit/risk 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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