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

Levamole Hydrochloride 75 mg/ml Oral Solution

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Levamole Hydrochloride 75 mg/ml Oral Solution
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd
Active substance(s)	Levamisole Hydrochloride
ATC Vetcode	QP52AE01
Target species	Cattle and Sheep
Indication for use	A broad spectrum anthelmintic for the treatment and control of gastro-intestinal and pulmonary nematode infections in cattle and sheep, effective against mature and developing immature stages of the following Levamole-susceptible major nematode worm species: **Gastro-intestinal Worms:** *Trichostrongylus* spp., *Cooperia* spp., *Ostertagia* spp. (except inhibited Ostertagia larvae in cattle), *Haemonchus* spp., *Nematodirus* spp., *Bunostomum* spp., *Oesophagostomum* spp., *Chabertia* spp. **Lungworms:** *Dictyocaulus* spp. Not effective against Type II winter scour.

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 Chanaverm 7.5% Oral Solution. The initial application for Chanaverm 7.5% Oral Solution 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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