IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Chanimec 10 mg/ml solution for injection for Cattle, Pigs and Sheep

PRODUCT SUMMARY

EU Procedure number	IE/V/0106/001
Name, strength and pharmaceutical form	Chanimec 10 mg/ml Solution for Injection for Cattle, Pigs and Sheep
Active substance	Ivermectin
Marketing Authorisation Holder	Chanelle Pharmaceuticals Manufacturing Limited
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	21st September 2000
Target species	Cattle, pigs, sheep
Indication for use	Treatment of infections with the following parasites in beef and non-lactating dairy cattle, pigs and sheep: **Cattle:** **Gastro-intestinal roundworms** (adult and fourth stage larvae): *Ostertagia spp.* (including inhibited *O.ostertagi)* *Haemonchus placei* *Trichostrongylus axei* *Trichostrongylus colubriformis* *Cooperia spp.* *Oesophagostomum radiatum* *Nematodirus helvetianus (*adult*)* *N. spathiger* (adult) **Lungworms** (adult and fourth stage larvae): *Dictyocaulus viviparus.* **Warbles**: *Hypoderma bovis* *H. lineatum.* **Mange mites:** *Psoroptes bovis* *Sarcoptes scabiei* var. *bovis.* **Sucking lice:** *Linognathus vituli* *Haematopinus eurysternus* The use of the product in cattle should take into account geographical differences in the occurrence patterns of parasites. **Pigs:** **Gastrointestinal roundworms**: (adult and fourth stage larvae): *Ascaris suum* *Hyostrongylus rubidus* *Oesophagostomum* spp. *Strongyloides ransomi* (adult only) **Lungworms:** *Metastrongylus* spp. (adult) **Lice:** *Haematopinus suis* **Mange mites:** *Sarcoptes scabiei* var. *suis* **Sheep:** **Gastrointestinal roundworms (adult and fourth-stage**

	larvae): *Teladorsagia circumcincta including inhibited larvae* *T. trifurcata* *Haemonchus contortus including inhibited larvae* *Trichostrongylus axei (adults)* *T. colubriformis and T. vitrinus (adults)* *Cooperia curticei* *Oesophagostomum columbianum* *O. venulosum (adults)* *Nematodirus filicollis* *Chabertia ovina* *Trichuris ovis (adults)* **Lungworms:** *Dictyocaulus filaria* (adult and fourth-stage larvae) *Protostrongylus rufescens* (adults) **Nasal bots (all larval stages) :** *Oestrus ovis.* **Mange mites:** *Psoroptes ovis*
ATC vet code	QP54AA01
Concerned Member States	BE, CZ, EL, FR, HU, NL, PL, PT, UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland. The Summary of Product Characteristics (SPC) for this product is available on the HPRA website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to Section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. 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.

VI. 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 HPRA website.
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 product.

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	**Approval date**
Addition of target species – sheep (IE/V/0106/1/A/011)	16/08/2023