IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Sumex 5 mg/ml Pour on Solution for Cattle

PRODUCT SUMMARY

EU Procedure number	IE/V/0209/001/MR
Name, strength and pharmaceutical form	Sumex Pour-on Solution 5 mg/ml for Cattle
Active substance(s)	Ivermectin
Applicant	Chanelle Pharmaceuticals Manufacturing Limited, Loughrea, Co. Galway, Ireland
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	26th September 2007
Target species	Cattle
Indication for use	For the treatment of gastrointestinal roundworms, lungworms, warbles, mites and lice
ATCvet code	QP54AA01
Concerned Member States	EL, ES, IT

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the 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 Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. 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's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product 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 product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

Composition of the Veterinary Medicinal Product
Active
Ivermectin 0.5% w/v

Excipients
Triethanolamine
Crodamol CAP
Isopropyl alcohol

Container/Closure System

1 L, 2.5 L, 5 L and 6 L (5 L and 1 L presentation) flat bottomed flexi pack containers and 250 ml, 500 ml and 1 L squeeze-measure containers. The 1 litre flexi pack containers are provided with a dial-a-dose dosing cup.

Clinical Trial Formula(e)
The formulation of the batches used in key clinical studies is identical to that proposed for marketing.

Development Pharmaceutics
The formulation is based on the formulation of the reference product Ivomec Classic Pour-on for Cattle obtained from the freedom of information summary of the FDA New Animal Drug Application.As this product was demonstrated to be bioequivalent to the reference product no development work/formulation optimisation was carried out.

B.Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C.Control of Starting Materials

Active Substance
The active substance is ivermectin, an established substance described in the European Pharmacopoeia. Batch analytical data demonstrating compliance with the Ph.Eur. specification have been provided.
The active substance is manufactured in accordance with the principles of good manufacturing practice.

Packaging Materials
The product is packaged in flexi-packs consisting of a HDPE container and a polypropylene closure or in HDPE squeeze measure pour containers with HDPE closures. The packaging materials comply with relevant EU standards.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D.Control on Intermediate Products

Not applicable.

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 product.

Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance withe the specification.

F.Stability

Stability Studies on the Active Substance

A suitable retest period for the active substance has been assigned based on the data provided.

Stability Tests on the Finished Product

Stability data on the product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G.Other Information

Not applicable.

Conclusion on Quality

The manufacture of the product is adequately described and controlled.Testing methods and specifications for the raw materials and packaging components are acceptable.The control tests and specifications for the finished product are appropriate.The shelf life and storage conditions are supported by appropriate stability data.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing
Pharmacological Studies
As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacodynamic tests are not required.

Pharmacokinetics
The applicant has conducted a pharmacokinetic study in cattle in accordance with the relevant Guideline, which shows that the product is bioequivalent to Ivomec Classic Pour-On for Cattle (Merial).

Toxicological Studies

The toxicological aspects of this product are identical to the reference product.
Studies on Metabolites, Impurities, Other Substances and Formulation.
The excipients included in the formulation are commonly used in topical veterinary pharmaceuticals.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.Warnings and precautions included on the product literature are the same as those of the reference product and are adequate to ensure safety to users when the product is used as directed.

Environmental Risk Assessment

The applicant has provided an environmental risk assessment for the product.This includes bibliographic data which support the relevance of the warnings and precautions.Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety to the environment when the product is used as directed.

III.BResidues Documentation

Precise Identification of the Product concerned by the Application
The product is intended for use in cattle.It contains 0.5% ivermectin and is to be administered topically as a single dose.

Residue Studies

A residue depletion study using the final formulation has been conducted in cattle. Tissues were taken from animals at several time points. Results show that residues depleted to below the MRL in all tissuesbefore the end of the withdrawal period

MRLs

Ivermectin is listed in Annex I of Council Regulation 2377/90The marker substance is 22,23-dihydroavermectin B1a.
MRLs are listed below:

	Cattle
Liver	100 µg/kg
Kidney	100 µg/kg
Fat	30 µg/kg

Withdrawal Periods

Based on the data provided above, a withdrawal period of 28 days for meat is justified. This corresponds to the withdrawal period of the reference product.
Analytical Methods used
The analytical method was by HPLC with fluorescence detection.
The method was fully validated.

IV. CLINICAL ASSESSMENT

Tolerance in the Target Species of Animals

The applicant has conducted a controlled target animal tolerance study using multiples of the recommended dose in cattle. The control group was untreated. All doses were administered topically on a single occasion or daily for 3 days.
Parameters evaluated were physical, local, haematological and biochemical.
No adverse effects were seen following doses up to 3 times the recommended dose
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

The resistance aspects of this product are identical to the reference product.
Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

V. 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.

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:
None.