IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Ovimectin 10 mg/ml Solution for Injection for Sheep

PRODUCT SUMMARY

EU Procedure number	IE/V/0215/001/MR
Name, strength and pharmaceutical form	Ovimectin 1 % w/v Solution for Injection
Active substance	Ivermectin
Applicant	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Airton Road Tallaght Dublin 24 Ireland
Legal basis of application	Generic application in accordance with Article 13 of Directive 2001/82/EC as amended.
Date of completion of procedure	24th October 2007
Target species	Sheep
Indication for use	For the treatment of gastro-intestinal roundworms, lungworms and grubs
ATCvet code	QP54AA01
Concerned Member State	ES

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 that may be 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

The product contains 10 mg/ml of ivermectin as the active substance and the excipients glycerol and glycerol formal.

The container/closure system consists of high-density polyethylene bottles of 50 ml, 250 ml or 500 ml.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

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

The active substance is ivermectin, an established substance described in the European Pharmacopoeia. 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 has been provided.

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 with the specification.

F. Stability

Stability data on the active substance has 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 has 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.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

The application is made in accordance with Article 13(1) of Directive 2001/82/EC as amended, therefore basic pharmacological and toxicological data relating to the active substance are not required.

Data provided in support of the application show that, following a single administration to sheep at a dose of 200 µg ivermectin/kg, the test product (Ovimectin Injection) is bioequivalent to the reference product (Panomec Injection); consequently, it can be concluded that the systemic effects of the two products in respect of safety and efficacy will be the same following a single administration.

Based on the user safety evaluation provided, the user risks associated with the use of this product are considered to be minimal and the proposed user warning statements are considered appropriate.

It is accepted that this product, when used in accordance with label recommendations, will not pose any greater risk to the environment that the reference product or related ivermectin injectable products.

III.B Residues Documentation

Residue Studies

A residue depletion study using the final formulation was conducted in sheep.The proposed withdrawal periods of 42 days for sheep is justified based on the data provided. In accordance with Regulation (EU) 37/2010, ivermectin is contraindicated for use in animals producing milk intended for human consumption and in accordance with current recommendations a withdrawal time of 60 days for dry dairy sheep applies.

IV. CLINICAL ASSESSMENT

The application is made in accordance with Article 13(1) of Directive 2001/82/EC as amended (a generic application).

Data provided in support of the application show that, following a single administration to sheep at a dose of 200 µg ivermectin/kg, the test product (Ovimectin Injection) is bioequivalent to the reference product (Panomec Injection); consequently, it can be concluded that the systemic effects of the two products in respect of safety and efficacy will be the same following a single administration.

To further support the safety of the final formulation, the Applicant has provided the results of a study that demonstrates that the product is well tolerated systemically when administered at up to 3 times the recommended treatment dose. Local injection site reactions were recorded; typically, these are mild and resolve without treatment.

The proposed SPC (in terms of indications/recommendations for use and target animal safety statements) reflects the authorised SPC of the reference product in the RMS.

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.