IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Ovisect 12.5 mg/ml Pour-On Solution for Sheep

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Ovisect 12.5 mg/ml Pour-On Solution for Sheep
Active substance(s)	Cypermethrin High:Cis (80:20)
Applicant	Bimeda Animal Health Limited, 2, 3 & 4 Airton Close, Airton Road, Tallaght, Dublin 24, Ireland
Legal basis of application	Generic application submitted in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of Authorisation	4th July 2013
Target species	Sheep
Indication for use	For the treatment and control of headflies, and treatment of ticks and biting lice in sheep. For the prevention and treatment of blowfly strike in sheep.
ATCvet code	QP53AC08

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 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 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 Qualitative Particulars

The product contains cypermethrin High:Cis (80:20) and the excipients green s dye (E142) and diethylene glycol monobutyl ether.
The container/closure system is a white high-density polyethylene flat bottom container with polypropylene closures.

The choice of the formulation and absence of preservative is justified.

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 cypermethrin high:cis (80:20),an established active substance. 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

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological, toxicological and residues tests were not required.

The quantitative and qualitative aspects of this product are identical to the reference product. Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

III.ASafety Testing

User Safety

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

III.B Residues Documentation

MRLs

Cypermethrin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows: The marker substance is cypermethrin (sum of isomers).

	All ruminants
Muscle	20 µg/kg
Liver	20 µg/kg
Kidney	20 µg/kg
Fat	200 µg/kg
Milk	20 µg/kg

Withdrawal Periods

The withdrawal period is same as the reference product, meat and offal 8 days. The product is not to be administered to animals producing milk for human consumption.

IV. CLINICAL ASSESSMENT

Ovisect 12.5 mg/ml Pour-On Solution for Sheep was demonstrated as being quantitatively and qualitatively same as the reference product, Crovect 1.25% w/v.Exemption from providing bioequivalence studies under condition 7 d) of the Guidelines for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products was accepted.

IV.A Pre-Clinical Studies(pharmaceuticals only)

Pharmacology

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of pharmacological tests are not required.

The pharmacological aspects of this product reflect those of the reference product.

Tolerance in the Target Species of Animals

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

Ovisect 12.5 mg/ml Pour-On Solution for Sheep was demonstrated as being quantitatively and qualitatively same as the reference product, Crovect 1.25% w/v.Exemption from providing bioequivalence studies under condition 7 d) of the Guidelines for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products was accepted. As this is a generic application in accordance with Article 13(1), exemption from providing any data on this section was considered acceptable.

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.

None.