Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vectocert 1.25% w/v Pour-On Solution for Sheep

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Vectocert 1.25% w/v Pour-on Solution for Sheep
Applicant	Bimeda Animal Health Limited Broomhill Road 2 / 3 / 4 Airton Close Tallaght Dublin 24 Ireland
Active substance(s)	Cypermethrin High:Cis (80:20)
ATC Vetcode	QP53AC08
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.

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	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

This was a generic application for which the reference product is Crovect 1.25% Pour-On Solution for Sheep which was authorised in the UK in 2001 and is a national informed consent product as a copy of Young's Vector which was first authorised in the UK in 1996 but is no longer marketed.

An exemption from the requirement for bioequivalence studies has been claimed in accordance with exemption 4.c) of the Guidelines for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMEA/CVMP/016/00-corr-FINAL).

The indication for Vectocert 1.25% Pour-On Solution for Sheep is for the treatment and control of headflies, and treatment of ticks and biting lice in sheep, and for the prevention and treatment of blowfly strike in sheep. It should be administered by the recommended applicator gun.

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 risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains cypermethrin high:cis (80:20) and excipients green dye (E142), and butyl dioxitol. The absence of preservative is justified.

The container/closure system is a white high density polyethylene flat bottom container with polypropylene closure and induction heat sealed wadding, in 1 litre, 2.5 litre, and 5 litre pack sizes. The particulars of the containers and controls performed are provided and conform to the regulation.

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 from a licensed manufacturing site.

The manufacturing process consists of dissolving cypermethrin high cis (80:20) in butyl dioxitol, mixing with green dye (E142) and then filling into the containers.

Process validation data on three commercial scale batches of the the product have 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 specification is considered adequate to control the quality of the material. The active substance is manufactured in accordance with the principles of good manufacturing practice and in accordance with an Active Substance Master File (ASMF). The excipients green dye (E142) and butyl dioxitol are manufactured in accordance with the manufacturer's specifications.

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

A declaration has been provided stating that the finished product complies with the latest version of the Committee for Proprietary Medicinal Products (CPMP)/ Committee for Medicinal Products for Veterinary Use (CVMP) TSE guideline.

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

E. Control on intermediate products

Not applicable.

F. 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 have been provided. Batch analytical data for 3 pilot scale batches have been provided demonstrating compliance with the specification. Tests include those for appearance, cypermethrin assay, cypermethrin impurities, water content, and specific gravity.

G. Stability

Stability data on three batches of the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on 3 batches of the finished 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.

H. Genetically Modified Organisms

Not Applicable.

J. Other Information

The application was supported with regard to quality. The following precautions are included on the SPC and product literature:

Do no store above 25°C
Protect from direct sunlight.
Store in tightly closed original container.
Store away from food, drink, and animal feeding stuffs.

The finished product has a shelf-life of 24 months, and an in-use shelf-life of 3 months.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and an exemption from bioequivalence studies under 4c) of EMEA/CVMP/016/00 has been permitted, results of bioequivalence studies are not required. The SPCs of these products are identical to the reference products.

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.A Safety Testing

Pharmacological Studies

As this is a generic application submitted according to Article 13(1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed because of the nature of the product, results of pharmacological studies are not required.

Toxicological Studies

As this is a generic application submitted according to Article 13(1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed because of the nature of the product, results of Toxicological studies are not required.

User Safety

The product has been demonstrated as quantitatively and qualitatively the same as 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 to users of the product. These warnings are:

- This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity (allergic) reactions. People with known hypersensitivity to cypermethrin should avoid contact with the product.
- Handle this product with great care to avoid accidental exposure.
- Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.
- Wear a disposable mask when applying as a fan-spray for the prevention of blowfly-strike.
- Use in a well-ventilated area and avoid inhaling the vapour.
- Do not eat, drink or smoke whilst using the product.
- Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.
- Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.
- Wash hands and exposed skin before eating, drinking or smoking and after work.
- In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.
- Avoid handling treated animals.

Ecotoxicity

The applicant provided a Phase II environmental risk assessment in compliance with the relevant guideline. The assessment concluded that the use of Vectocert 1.25% w/v Pour On is not expected to pose a risk for the environment when used as described in the SPC. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed. These warnings are:

- As a precautionary measure sheep must be kept away from watercourses for at least one hour following treatment.
- Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung

insects. Long term effects on dung insects caused by continuous or repeated use of the product cannot be excluded.

III.B Residues documentation

As this is a generic application according to Article 13, and an exemption from bioequivalence studies under 4c) of EMEA/CVMP/016/00 has been permitted, residues studies are not required.

Withdrawal Periods

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

IV CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and an exemption from bioequivalence studies under 4c) of EMEA/CVMP/016/00 has been permitted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

As this is a generic application according to Article 13, and an exemption from bioequivalence studies under 4c) of EMEA/CVMP/016/00 has been permitted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.B Clinical Studies

As this is a generic application according to Article 13, and an exemption from bioequivalence studies under 4c) of EMEA/CVMP/016/00 has been permitted, 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.

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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