IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Deltadot 10 mg/ml Pour-on Solution for Cattle and Sheep

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Deltadot 10 mg/ml Pour-on Solution for Cattle and Sheep
Active substance	Deltamethrin
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(1) of Directive 2001/82/EC as amended.
Date of Authorisation	02 September 2016
Target species	Cattle and sheep
Indication for use	Prevention and treatment of infestations by the following external parasites: On cattle: For the treatment and prevention of infestations by both sucking and biting lice, including *Bovicola bovis, Solenopotes capillatus, Linognathus vituli* and *Haematopinus eurysternus*. Also as an aid in the treatment and prevention of infestations by both biting and nuisance flies including *Haematobia irritans, Stomoxys calcitrans, Musca* species and *Hydrotaea irritans*. On sheep: For the treatment and prevention of infestations by ticks *Ixodes ricinus*and by lice (*Linognathus ovillus, Bovicola ovis*), keds (*Melophagus ovinus*) and established blowfly strike (usually *Lucilia* spp.). On lambs: For the treatment and prevention of infestations by ticks *Ixodes ricinus* and by lice *Bovicola ovis*.
ATCvet code	QP53AC11

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

The product contains the active substance deltamethrin10 mg/ml and the excipient triglycerides, medium chain.
The container/closure system is a high density polyethylene flexipack with twin neck dispenser, internal graduated calibration chamber and polypropylene heat-sealed screw cap or a high-density polyethylene flat bottom container with polypropylene closure and induction heat-sealed wadding.
The 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 in accordance with European guidelines is provided.

C. Control of Starting Materials

The active substance is deltamethrin an established substance described in the British Veterinary 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

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 tests 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 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

Pharmacological Studies

The test product can be considered bioequivalent with the reference product VERSATRINE. According to the current bioequivalence guideline (EMEA/CVMP/016/00-Rev.2), the exemption of bioequivalence studies can be granted because, the conditions stated in paragraph 7.1.d) are fulfilled.

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

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

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

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was required for cattle and sheep on pasture because the product is an ectopararsiticide. A phase II environmental risk assessment was provided.

The assessment concluded that that deltamethrin is toxic to dung insects,aquatic organisms, is persistent in soils and may accumulate in sediment.

As such appropriatewarnings are included in the product literature:

iii) Other precautions

Deltamethrin is very toxic to dung, fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.
The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep,e.g. by using only a single treatment per year on the same pasture.
The risk to aquatic ecosystems will be further reduced by preventing treated sheep from entering watercourses for one hour immediately after treatment.

5.1 Environmental properties

Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of potentially toxic levels of deltamethrin may take place over a period of 4 weeks Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.
Deltamethrin has been shown to be persistent in soil.

III.B Residues Documentation

Residue Studies

No depletion study was performed with the tested product.

MRLs

Deltamethrin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

	All ruminants	**Fin fish**
Muscle	10 µg/kg	10 µg/kg
Liver	10 µg/kg	-
Kidney	10 µg/kg	-
Fat	50 µg/kg	-
Milk	20 µg/kg	-

Withdrawal Periods

No residue depletion studies were conducted because the product is generic and has been shown to be bioequivalent to the reference product.
The following withdrawal periods are accepted:

Cattle
Meat and offal – 18 days
Milk – zero hours

Sheep
Meat and offal – 35 days
Milk – 24 hours

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies
Tolerance in the Target Species of Animals

No tolerance study has been conducted with the test product.

As the composition of the test product is similar to the one of the reference product and bioequivalence with the reference product can be assumed, specific tolerance studies are not required.

The type and incidence of adverse effects presented in the product literature are equivalent as that of the reference product SPC.

IV.B Clinical Studies
As this is a generic application according to Article 13(1), 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.