IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Endofluke 100 mg/ml Oral Suspension

PRODUCT SUMMARY

EU Procedure number	IE/V/0141/001/MR
Name, strength and pharmaceutical form	Endofluke 100 mg/ml Oral Suspension
Active substance(s)	Triclabendazole
Applicant	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Airton Road Tallaght Dublin 24
Legal basis of application	A hybrid generic application in accordance with Article 13.3 of Directive 2001/82/EC as amended.
Date of completion of procedure	20th February 2003
Target species	Cattle and Sheep
Indication for use	For the treatment of adult, immature and early immature stages of liver fluke (*Fasciola hepatica*) susceptible to triclabendazole
ATCvet code	QP52ACO1
Concerned Member States	DE, UK

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

This assessment report concerns the extension of the marketing authorisation of the currently authorised product for use in cattle to include sheep as an additional target species.
The initial marketing authorisation was granted before there was a requirement for a publicly available assessment report and therefore no details of the original assessment report are provided.
It has been shown that the product can be safely used in the new 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 in accordance with the relevant guidelines and according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting an extension to the marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars
The product contains 10% w/v triclabendazole and the excipients xanthan gum, methyl parahydroxybenzoate, propyl parahydroxybenzoate, citric acid anhydrous, sodium citrate, polysorbate 80, silica colloidal, anhydrous simethicone emulsion and water, purified.
The initial marketing authorisation was granted before there was a requirement for a publicly available assessment report and therefore no details of the original assessment report are provided in this section.

The product is an established pharmaceutical form.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The initial marketing authorisation was granted before there was a requirement for a publicly available assessment report and therefore no details of the original assessment report are provided in this section.
As the addition of sheep is considered as an extension application to a generic product according to Article 13, and bioequivalence with a reference product (Fasinex 5% Oral Suspension) has been demonstrated, results of safety and residues tests and of pre-clinical and clinical trials are not required.
The safety and efficacy aspects of this product when used in sheep are identical to the reference product.
Warnings and precautions as listed on the product literature are in line with those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers.

III.A Safety Testing

The applicant has conducted an *in vivo* bioequivalence study, comparing the bioavailability of triclabendazole in Endofluke 100 mg/ml Oral Suspension with the reference product Fasinex 5% Oral Suspension (Novartis). The results of this study demonstrated that Endofluke 100 mg/ml Oral Suspension is bioequivalent to the reference product in accordance with the relevant guidelines.

User Safety

Given that bioequivalence has been demonstrated with the reference product, any risk to user safety will be the same as that for the reference product.
The exposure scenarios and the quantity of product to which the user may be exposed will be similar regardless of whether the product is used in cattle or sheep. Consequently, this product will not present any greater risk to the user by virtue of its use in sheep relative to its current use in cattle.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided an environmental impact assessment considering the effects on the environment resulting from the addition of sheep as a target species in accordance with the relevant guidelines. The assessment concluded that no increased exposure of the environment would result from the extension of the use of the product to sheep.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

No residue depletion studies were conducted in sheep because bioequivalence has been demonstrated with the reference product and the withdrawal periods of the reference product can be applied to Endofluke 100 mg/ml Oral Suspension.

Withdrawal Periods

The withdrawal period for sheep meat and offal has been accepted as 56 days.
Based on the bioequivalence data provided, a withdrawal period of 56 days for meat in sheep is justified.

IV. CLINICAL ASSESSMENT

As the extension of the current marketing authorisation to include sheep as an additional target species is submitted as 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.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals
Based on bioequivalence data presented, it is considered that the test product does not present any greater risk to the target species sheep than the reference product.

Resistance
Adequate warnings and precautions appear on the product literature.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier of the extension application to include sheep as target species has demonstrated that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the sheep as a new 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.

Safety/efficacy changes

Summary of change (Type; application number)	**Section updated in Module 3**	**Approval date**
Addition of target species - sheep (IE/V/0141/001/X/001)	IIIA IIIB IV	30th September 2009.