IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Profen Equine 100 mg/ml oral suspension for horses.

PRODUCT SUMMARY

EU Procedure number	N/A
Name, strength and pharmaceutical form	Profen Equine 100 mg/ml oral suspension for horses.
Active substances(s)	Fenbendazole
Applicant	Interchem Ireland Ltd 29 Cookstown Industrial Estate Dublin 24 Ireland
Legal basis of application	Informed Consent application (Article 21 of Regulation (EU) 2019/6)
Date of Authorisation procedure	20/06/2024
Target species	Horses
Indication for use	For the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tract, including encysted mucosal small strongyle larvae (cyathostomes). The veterinary medicinal product has an ovicidal effect on roundworm eggs. For the treatment of horses infected with adult large strongyles and adult and larval small strongyles. For the treatment of ascarids and *Oxyuris equi*.
ATCvet code	QP52AC13
Concerned Member States	NA

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (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 47 of Regulation 2019/6 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 quality aspects of this product are identical to Curazole 100 mg/ml oral suspension for horses VPA 10990/015/004 which in turn is identical to Curazole 10 % w/v oral drench VPA 10990/015/001. The initial application for Curazole 10 % w/v oral drench was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.
The safety and efficacy aspects of this product are identical to Curazole 100 mg/ml oral suspension for horses VPA 10990/015/004, for which the public assessment report is available on the HPRA website.

II. QUALITY ASPECTS

See Part I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See Section 1.

IV. CLINICAL ASSESSMENT

See Section 1.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

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.