IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

EquiDaz Forte 100 mg/ml oral suspension for horses

PRODUCT SUMMARY

Name, strength and pharmaceutical form	EquiDaz Forte 100 mg/ml oral suspension for horses
Active substances(s)	Fenbendazole
Applicant	Duggan Veterinary Supplies Limited Unit 9 Retail Park Thurles Tipperary E41 E7K7 Ireland
Legal basis of application	Informed Consent application (Article 21 of Regulation (EU) 2019/6)
Date of completion of procedure	11/06/2025
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

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 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 quality, safety, and efficacy aspects of this product are identical to those of Curazole 100 mg / ml oral suspension for horses (VPA10990/015/004). Cross reference is therefore made to the public assessment report for Curazole 100 mg / ml oral suspension for horses.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data referenced 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.