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Post Authorisation Assessments

Gallifen 200 mg/ml Suspension for Use in Drinking Water for Chickens and Pheasants

Vm 30282/5003

•	12 March 2024	NRA type C.8. to include the withdrawal period for
		pheasant eggs again in the product literature.
•	18 January 2024	Addition of an indication for adult stages of Raillietina echinobothrida at a dose of 3.0 mg fenbendazole per kg body weight per day.
		Alignment of the product information with version 9.0* of the QRD templates.
•	26 September 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer.
•	22 July 2022	Unlimited renewal.
•	21 October 2021	Addition of a new therapeutic indication.
•	13 August 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 April 2021	Minor change in the manufacturing process of the finished product. Addition of a specification parameter with its corresponding test method of the finished product.
•	30 May 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	20 February 2019	Variation extension to add Pheasants as a target species