Veterinary Medicines Directorate

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Post Authorisation Assessments

Draxxin Plus 100 mg/ml + 120 mg/ml Solution for Injection for Cattle

Vm 42058/3002

•	10 April 2024	Addition of a secondary packaging site for the finished product. Addition of a secondary packaging site for the finished product.
•	13 October 2023	Minor change in the manufacturing process of the finished product, including editorial changes for increased clarity.
•	04 July 2023	Submission of an updated certificate of suitability.
•	31 March 2023	Change(s) in the SPC, labelling or package leaflet to sections 4.6 and 6. Alignment of the product information with version 9.0* of the QRD templates.
•	19 August 2022	Change in the batch size of the finished product.
•	08 February 2022	Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture
•	05 August 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 November 2020	Minor changes to an approved test procedure of the finished product.