



Post Authorisation Assessments

Equipalazone 1 g Oral Powder for Horses and Ponies Vm 10434/5017

•	02 May 2023	Addition of a new in-process test and limits applied during the manufacture of the finished product. (NI)
•	10 March 2023	Addition of a new in-process test and limits applied during the manufacture of the finished product. (GB)
•	23 January 2023	Editorial changes to part 2 of the dossier.
•	11 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	05 October 2022	Renewal
•	22 September 2022	Updated certificate of suitability from an already approved manufacturer.
•	23 August 2022	Editorial changes to part 2E of the dossier.
•	21 January 2022	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
•	22 September 2021	Change in immediate packaging of the active substance.
•	29 July 2021	Change in the address (postcode) of the manufacturer of the finished product.
•	04 September 2020	Change to in-process tests applied during the manufacture of the finished product.
•	14 April 2020	Addition of components (excipients) of the flavouring or colouring system of the finished product.
•	06 February 2020	Change to the name of the product in the UK only to Equipalazone 1 g Oral Powder for Horses and Ponies.
•	07 January 2020	Minor change in the manufacturing process of the finished product.
•	18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	18 March 2019	Change in RMS from UK to BE.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	05 October 2017	Minor change in the manufacturing process of the finished product. Minor adjustments of the quantitative composition of the finished product with respect to excipients.
•	05 October 2017	Change in the invented name of the veterinary medicinal product from Equipalazone 1 g Oral Powder for Horses and Ponies to Fenylbutazon 1 g Oral Powder for Horses and Ponies in the UK only