



Post Authorisation Assessments

Equipalazone 1 g Oral Powder for Horses and Ponies

Vm 50406/3019

13 February 2025	Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
03 January 2025	Alignment of product information with version 9.0 of the QRD templates.
20 October 2024	Deletion of a test procedure. Deletion of a non-significant specification parameter for the finished product. Deletion of a non-significant specification parameter for the finished product. Editorial change to part 2 of the dossier.
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