



Post Authorisation Assessments

Butaleve 1 g Oral Powder for Horses and Ponies

Vm 10434/4098

•	07 December 2023	Unlimited renewal
•	13 March 2023	Addition of a new in-process test and limits applied during the manufacture of the finished product.
•	20 December 2022	Editorial changes to part 2 of the dossier.
•	23 November 2022	Editorial changes to part 2 of the dossier.
•	22 August 2022	Editorial changes to part 2B of the dossier.
•	21 July 2022	Deletion of a test procedure for the active substance. Deletion of a test procedure for the active substance.
•	10 February 2022	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
•	25 June 2021	Change in the address of the manufacturer of the finished product.
•	25 March 2021	Change in immediate packaging of the active substance.
•	03 December 2019	Minor change in the manufacturing process of the finished product.