Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Butador 10 mg/ml Solution for Injection for Horses, Dogs and Cats

Vm 57446/5006

•	October 2024	One-off alignment of the product information with version 3 of the GB SPC/QRD template.
•	23 November 2024	Deletion of a supplier of packaging components or devices.
•	03 November 2023	Change in distributor details from Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ to Chanelle Vet UK Ltd, 483 Green Lanes, London, N13 4BS.
•	14 June 2023	Change in the batch size of the finished product: - Other changes. (NI)
•	22 March 2023	Change in the specification parameters and/or limits of an active substance Where there is no monograph in the European Pharmacopoeia or the national pharmacopoeia of a Member State for the active substance. Minor change to the restricted part of an Active Substance Master File.
•	14 March 2023	Change in the batch size (including batch size ranges) of the finished product. (GB)
•	07 March 2023	Change in the specification parameters and/or limits of an active substance Where there is no monograph in the European Pharmacopoeia or the national pharmacopoeia of a Member State for the active substance. Minor change to the restricted part of an Active Substance Master File.
•	23 January 2023	Change in MAH from Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria to VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria.
•	21 March 2022	Changes to SPC & product literature following a Repeat Use procedure.
•	28 January 2022	Minor change to the restricted part of an Active Substance Master File.
•	05 June 2020	To update the ASMF.
•	07 August 2018	Changes to a test procedure for the finished product. Changes to a test procedure for the finished product.
•	29 June 2017	Repeat Use application to add 4 new member states
•	27 March 2017	Changes to the manufacturing process of the active substance in the Applicant's Part of the Active Substance Master File. Changes to the manufacturing process of the active substance in the Restricted Part of the Active Substance Master File.
•	27 April 2016	Submission of a Partial Update 8/2015 for the Applicant's Part and the Restricted Part from the ASMF folder for the active substance.

		Addition of an alternative supplier of the starting material
•	22 March 2016	Additional batch size of the finished product.
•	14 October 2015	Renewal
•	24 March 2015	Update to the currently approved active substance information.
•	16 October 2014	Minor change in test procedure for active substance. Change to the QPPV, the QPPV contact details and the QPPV back-up. Changes to the DDPS.
•	27 July 2011	To seek approval of the mock-ups and to obtain joint labelling with Ireland
•	08 June 2011	To change the name of the medicinal product from Buto 10 mg/ml solution for injection for horses, dogs and cats to Butador 10 mg/ml solution for injection for horses, dogs and cats.