



## Post Authorisation Assessments

### Gold Fleece Sheep Dip, 608 mg/ml Concentrate for Dip Emulsion Vm 50146/4031

•	22 March 2024	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	26 October 2023	Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes. Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes. Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes.
•	26 October 2023	Changes to the quality part of the dossier: Deletion of - a non-significant in-process test during the manufacture of the finished product
•	28 December 2022	Change to in-process tests or limits applied during the manufacture of the active substance: – addition of a new in-process test and limits.
•	16 November 2022	Replacement Quality Control site for the finished product.
•	24 November 2021	Minor change in the manufacturing process of an immediate release oral solutions. Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Minor adjustments of the quantitative composition of the finished product with respect to excipients. Minor change in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	02 July 2021	Changes to the labelling and package leaflet.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 August 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	15 August 2019	Change in the invented name of the veterinary medicinal product from Osmonds Gold Fleece Sheep Dip, 60.8% w/v Concentrate for Dip Emulsion to Gold Fleece Sheep Dip, 608 mg/ml Concentrate for Dip Emulsion. Changes to the labelling and package leaflet.
•	25 October 2018	Changes to an existing pharmacovigilance system as described in the DDPS.

		Change of MAH, from Cross Vetpharm Group Ltd, Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	11 June 2015	Change in name of the active substance.
•	03 October 2014	Deletion of a non-significant in-process test for the finished product.
•	29 April 2013	Replacement of an excipient with a comparable excipient.
•	29 April 2013	Reduction of meat withdrawal period from 70 days to 49 days.
•	18 April 2012	Update to an ASMF of an active substance.
•	24 May 2011	Change in the contact details for the National Poisons Information Service found on the SPC and product literature.
•	08 February 2010	Extension of meat withdrawal period from 35 to 70 days.
•	24 July 2008	Changes to the SPC and product literature to bring in line with new legislation.
•	24 July 2008	Change in legal category from PML to POM-VPS.
•	14 January 2008	Change in batch size of finished product.
•	22 December 2006	Renewal
•	30 October 2001	Changes relating to sterile container.