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Post Authorisation Assessments

Bovilis IBR Marker Live, Lyophilisate and Solvent for Suspension for Cattle

Vm 01708/5095

•	19 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
•	28 May 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	19 May 2021	Change in the address of the manufacturer of the
	10 May 2021	finished product.
•	17 July 2020	Change of MAH from Intervet International BV
		represented by: Intervet UK Ltd., Walton Manor, Walton,
		Milton Keynes, Buckinghamshire, MK7 7AJ to MSD
		Animal Health UK Limited, Walton Manor, Walton, Milton
	00 December 0047	Keynes, Buckinghamshire, MK7 7AJ.
•	22 December 2017	Changes to the labelling or package leaflet.
•	05 June 2017	Change in the SPC, labelling or package leaflet due to new data.
•	20 January 2017	Change of specification of a former non EU
		Pharmacopoeial substance of a starting material to fully
_	19 May 2016	comply with Ph.Eur. Change in the manufacturing process of the finished
•	18 May 2016	product.
•	08 October 2014	Deletion of selected pack sizes of solvent.
•	10 July 2014	Variation to introduce joint labelling between the UK and Ireland.
•	16 April 2014	Change in shelf life and manufacturing process of the
		finished product.
•	21 March 2013	Update of the SPC
•	20 April 2012	Change of manufacturer of the finished product
•	29 March 2012	Addition of a test performed on the active substance
		Changes of test procedure performed on the finished
_	04 July 2011	Additional manufacturing site of the active substance
•	04 July 2011 03 February 2010	Additional manufacturing site of the active substance
•	•	Minor changes to the Product Literature
	17 July 2009	Addition of a manufacturer of a component of the active substance
•	14 October 2008	Approval of previously unseen mock ups
•	20 December 2007	Change of starting materials
•	10 May 2007	Change of safety information (compatibility)
•	04 August 2006	Change of product name from 'Bovilis IBR Marker' to 'Bovilis IBR Marker Live'
•	21 July 2006	Renewal
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•	29 November 2005	Change of distributor
•	07 April 2003	Change in composition of the finished product