



Post Authorisation Assessments

Bovilis Leptavoid – H Suspension for Injection for Cattle Vm 01708/4568

•	20 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
•	19 November 2021	Change in the invented name of the veterinary medicinal product from Leptavoid–H Suspension for Injection for Cattle to Bovilis Leptavoid–H Suspension for Injection for Cattle. Changes to the labelling and package leaflet.
•	28 April 2021	Change in name of the MAH from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	09 April 2020	Change of a test procedure for the finished product.
•	04 October 2016	Approval of mock ups.
•	21 December 2015	General text and format update of SPC and PL text in line with recent QRD Addition of new immediate packaging material (PET) Addition of a new presentation (100 ml)
•	07 October 2014	Change in shape or dimensions of the container or closure (immediate packaging)
•	03 June 2011	Renewal.
•	12 January 2011	Change in the name of the Manufacturer.
•	24 November 2010	Change to SPC and Product Literature.
•	24 November 2010	Align the UK and Irish SPC and Product Literature.
•	15 September 2010	Change in the Marketing Authorisation Holder and Distributor.
•	26 May 2010	Change in the legal category from POM-V to POM-VPS.
•	09 May 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	24 October 2005	Reviewal of Marketing Authorisation.