Veterinary Medicines Directorate

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

Post Authorisation Assessments

Amfipen LA 100mg/ml Suspension for Injection

Vm 01708/4233

•	31 July 2023	Change in immediate packaging of the finished product.
•	09 June 2021	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	10 September 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 August 2017	Change in the specification limits of the finished product.
•	22 June 2016	Deletion of a manufacturer of the finished product.
•	23 September 2016	Update of the SPC and product literature to comply with QRD standards. Namely the addition of prudent use recommendations.
•	26 September 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
•	18 December 2008	Change in test procedure for the finished product.
•	25 October 2007	Submission of a new Ph. Eur. Certificate of Suitability for an active substance manufacturer.
•	04 July 2007	Increase in batch size.
•	11 July 2006	Addition of 100ml pack type.
•	23 May 2006	Updates to bring SPC and labels in line with new legislation.
•	22 May 2006	Renewal.
•	16 June 2005	Change of distributor.
•	16 June 2005	Addition of a new manufacturer, modification of the manufacturing method and changes to finished prodct specification.
•	02 November 2004	Renewal.
•	29 September 2004	Removal of indications for lactating cattle.
•	03 July 2001	Addition of a distributor.
•	02 June 2000	Change of address for the MAH.
•	19 November 1999	Change in product name from “Intacilin La” to “Amfipen LA”.
•	31 August 1996	Renewal.