Veterinary Medicines Directorate

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

Post Authorisation Assessments

Albiotic 330 mg / 100 mg Intramammary Solution

Vm 30282/4035

•	24 October 2022	Change in the batch size of the finished product:- The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes.
•	08 June 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 September 2021	Submission of a new certificate of suitability for an active substance.
•	04 August 2021	Replacement of a secondary packaging site of the finished product. Replacement to a test procedure for the finished product. Decrease in batch size range of the finished product. Replacement of a manufacturing site of the finished product. Changes in the manufacturing process of the finished product.
•	09 June 2021	Submission of a new certificate of suitability for an active substance.
•	22 August 2019	Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years. Change in storage conditions of the finished product.
•	17 April 2019	Replacement of a manufacturer responsible for batch release including batch control/testing.
•	22 December 2016	Change in the invented name of the veterinary medicinal product from Lincocin Forte S Intramammary Solution to Albiotic 330 mg / 100 mg Intramammary Solution.
•	09 March 2016	Change in distributor details. Change in legal entity
•	16 December 2015	To change the supplier of the immediate packaging To tighten a specification To add a second identity test To remove a testing To change the site of batch release To replace a secondary packaging site To change the batch size To replace the site of finished product manufacturing
•	04 July 2013	Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.
•	23 August 2012	Change to batch release arrangements and quality control testing for the finished product.
•	14 June 2012	Addition of a site of testing.

•	05 August 2009	Renewal.
•	15 May 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	28 February 2006	Change of Marketing Authorisation Holder name and address.
•	20 September 2005	Renewal.
•	14 July 2005	Change of Distributor.
•	22 March 2005	Change in the site of Active Substance manufacture.
•	21 January 2005	Change in the name of the Active Substance manufacturer.
•	28 August 2003	Addition of a Distributor.
•	24 July 2003	Variation to change container dimensions/shape.
•	24 January 2003	Change in the withdrawal period of the finished product.
•	24 January 2003	Change in the withdrawal period of the finished product.
•	22 August 2001	Change in the name of the Marketing Authorisation Holder.
•	05 January 2000	New Marketing Authorisation.