

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 Submission of a new certificate of suitability for an active substance. 04 August 2021 Submission of a new certificate of the finished product. Decrease in batch size range of the finished product. Changes in the manufacturing site of the finished product. Changes in the manufacturing site of the finished product. Changes in the manufacturing process of the finished product. Change in the shelf-life of the finished product. Change in the shelf-life of the finished product. Change in storage conditions of the finished product. 17 April 2019 Replacement of a manufacture responsible for batch release including batch control/testing. 22 December 2016 Change in the invented name of the veterinary medicinal product for Albiotic 330 mg / 100 mg Intramammary Solution. 09 March 2016 Change the supplier of the immediate packaging To tighten a specification To change the supplier of the invented manufacturing 16 December 2015 To change the supplier of the invented manufacturing 04 July 2013 Transfer of Marketing Authorisation Holder. Change in the name of the manufacturing 04 July 2013 Transfer of Marketing Authorisation Holder. Change in the name of the manufacturing 14 June 2012 Addition of a site of testing. 			
• 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. Changes in the manufacturing process 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. • 09 June 2021 Submission of a new certificate of suitability for an active substance. • 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. Change in storage conditions of the verinary medicinal product from Lincocin Forte S Intramammary Solution to Albiotic 330 mg / 100 mg Intramammary Solution. • 16 December 2015 To change the ster of batch release To replace a secondary packaging site To change the batch size To replace a secondary packaging site To change the batch size To replace a secondary packaging site To change the batch size To replace a secondary packaging site To change the batch size To replace a secondary packaging site To change the batch size To replace the site of finished product manufacturing • <th>•</th> <th>24 October 2022</th> <th>change relates to all other pharmaceutical forms</th>	•	24 October 2022	change relates to all other pharmaceutical forms
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. 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 moufacturer responsible for batch release including batch control/testing. 22 December 2016 Change in the invented name of the verterinary 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 To change the supplier of the immediate packaging To tighten a specification To add a second identity test To replace a secondary packaging site To change the batch size To replace a secondary packaging site To change the batch size 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 batc		08 June 2022	
• 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. Changes in the manufacturing process of the finished product. • 09 June 2021 Submission of a new certificate of suitability for an active substance. • 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 manufacture 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 site To replace a secondary packaging site To replace a secondary packaging site To replace a secondary packaging site 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 rele	•		an active substance from an already approved
• 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 the supplier of the immediate packaging To tighten a specification To add a second identity test To remove a testing • 16 December 2015 To change the site of batch release 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.			manufacturer.
• 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. 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 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.	•	24 September 2021	Submission of a new certificate of suitability for an active
 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 legal entity 16 December 2015 To change the supplier of the immediate packaging To tighten a specification To add a second identity test To replace a secondary packaging site To change the site of batch release 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. 			
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.• 09 June 2021Submission of a new certificate of suitability for an active substance.• 22 August 2019Increase 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 2019Replacement of a manufacturer responsible for batch release including batch control/testing.• 22 December 2016Change in the invented name of the veterinary medicinal product from Lincocin Forte S Intramammary Solution.• 09 March 2016Change in distributor details. Change in legal entity• 16 December 2015To change the supplier of the immediate packaging To tighten a specification To add a second identity test To remove a testing To change the batch release To replace the site of finished product manufacturing• 04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.• 23 August 2012Change to batch release arrangements and quality control testing for the finished product.	•	04 August 2021	
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 2021Submission of a new certificate of suitability for an active substance.•22 August 2019Increase 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 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change in details. Change in legal entity•16 December 2015To change the supplier of the immediate packaging To ighten a specification To add a second identity test To remove a testing To change the batch release To replace a secondary packaging site To change the batch size To replace the site of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			
Replacement of a manufacturing site of the finished product. Changes in the manufacturing process of the finished product.•09 June 2021Submission of a new certificate of suitability for an active substance.•22 August 2019Increase 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 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change the supplier of the immediate packaging To change the supplier of the immediate packaging To change the supplier of the immediate packaging 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 2013Transfer of Marketing Authorisation Holder. Change in release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			
product. Changes in the manufacturing process of the finished product.•09 June 2021Submission of a new certificate of suitability for an active substance.•22 August 2019Increase 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 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change in distributor details. Change in legal entity•16 December 2015To change the supplier of the immediate packaging To tighten a specification To add a second identity test To remove a testing To change the batch size To replace a secondary packaging site To replace the site of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			
Changes in the manufacturing process of the finished product.•09 June 2021Submission of a new certificate of suitability for an active substance.•22 August 2019Increase 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 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change in the invented name of the veterinary medicinal product from Lincocin Forte S Intramamary Solution to Albiotic 330 mg / 100 mg Intramammary Solution.•09 March 2016Change in legal entity•16 December 2015To change the supplier of the immediate packaging To tighten a specification To add a second identity test To replace a secondary packaging site To change the site of batch release To replace the site of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			· · · · · · · · · · · · · · · · · · ·
product.•09 June 2021Submission of a new certificate of suitability for an active substance.•22 August 2019Increase 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 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change in distributor details. Change in legal entity•16 December 2015To 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 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for 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 • 04 July 2013 Transfer of Marketing Authorisation Holder. Change in the name of the manufacturing • 23 August 2012 Change to batch release arrangements and quality control testing for the finished product.			•
• 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 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.	•	09 June 2021	
packaged for sale, from 2 to 3 years. Change in storage conditions of the finished product.•17 April 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change in distributor details. Change in legal entity•16 December 2015To 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 change the batch size To change the batch size To change the set of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			-
Change in storage conditions of the finished product.•17 April 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change in distributor details. Change in legal entity•16 December 2015To change the supplier of the immediate packaging To tighten a specification To remove a testing To change the site of batch release To replace a secondary packaging site To replace the site of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.	•	22 August 2019	
•17 April 2019Replacement of a manufacturer responsible for batch release including batch control/testing.•22 December 2016Change 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 2016Change in distributor details. Change in legal entity•16 December 2015To 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 replace the site of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			
Image: constraint of the section of			
• 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.	•	17 April 2019	
product from Lincocin Forte S Intramammary Solution to Albiotic 330 mg / 100 mg Intramammary Solution.•09 March 2016Change in distributor details. Change in legal entity•16 December 2015To 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 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			
Albiotic 330 mg / 100 mg Intramammary Solution.•09 March 2016Change in distributor details. Change in legal entity•16 December 2015To 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 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.	•	22 December 2016	
•09 March 2016Change in distributor details. Change in legal entity•16 December 2015To 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 replace the site of finished product manufacturing•04 July 2013Transfer of Marketing Authorisation Holder. Change in the name of the manufacturer responsible for batch release.•23 August 2012Change to batch release arrangements and quality control testing for the finished product.			•
 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. 		00 Marsh 2010	
 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 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. 	•	U9 March 2016	
 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. 		16 December 2015	
 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 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. 	•	To December 2015	
 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. 			
 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. 			-
• 23 August 2012 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.			
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.			•
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.			
 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. 			
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.	•	04 July 2013	· · · · · · · · · · · · · · · · · · ·
release. • 23 August 2012 Change to batch release arrangements and quality control testing for the finished product.			
control testing for the finished product.			•
	•	23 August 2012	Change to batch release arrangements and quality
14 June 2012 Addition of a site of testing.			
	•	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.