Veterinary Medicines Directorate

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Post Authorisation Assessments

Cobactan MC Intramammary Suspension 75mg Milking Cow

Vm 01708/4444

•	11 May 2024	Minor change to the restricted part of an Active Substance Master File. Changes in the manufacturing process of the active substance.
•	13 February 2024	Addition of a manufacturing site responsible for batch release. Introduction of registered pack size into market.
•	15 November 2022	Change in the address details of a manufacturer of the active substance.
•	19 August 2022	Change of the weight, type and thickness of the sachets in which the cleaning towels are packaged.
•	22 February 2022	Minor changes to an approved test procedure. Tightening limit on single impurity specification limits. Addition of new specification parameter for unidentified impurities. Addition of known impurities specifications to release specification.
•	07 May 2021	Update to the ASMF.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	02 December 2020	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	02 July 2019	Reduction of the shelf life of the finished product as packaged for sale from 30 months to 24 months.
•	03 June 2014	Variation to change the withdrawal period for Cobactan MC from, Meat: 2 days and Milk: 3.5 days (84 hours) to Meat and offal: 4 days and Milk: 5 days (120 hours). In addition, when used in combination with Cobactan 25 mg/ml, the withdrawal periods for Cobactan MC have been amended from, Meat: 5 days, Milk: 3.5 days (84 hours) to Meat and offal: 5 days and Milk 5 days (120 hours).
•	14 September 2011	Addition of a site for part of the manufacturing process of the active substance
•	12 August 2011	Deletion of a manufacturer of the active substance
•	10 November 2010	Change to composition of the packaging material
•	18 December 2009	Change in batch size
•	26 November 2009	Minor change in manufacturing process of the active substance

•	09 November 2009	Changes to test procedures performed on the active substance
•	29 October 2009	Changes to test procedures performed on the finished product
•	14 October 2008	Change in legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	21 May 2008	Change of product name from 'Cephaguard LC' to 'Cobactan MC Intramammary Suspension 75mg Milking Cow'
•	01 November 2006	Renewal
•	20 June 2005	Distributor
•	29 September 2004	Addition of a 30 syringe pack size
•	20 July 2004	Addition of a manufacturing site for an intermediate used in the manufacture of the active substance
•	25 February 203	Addition of a manufacturer of the dosage form
•	17 January 2003	Change of product name from 'Cephaguard LC Intramammary' to 'Cephaguard LC'
•	19 November 2002	Renewal
•	19 June 2002	Addition of site of manufacturing, filling and secondary packaging for the finished product Change in batch size
•	08 March 2002	Additional pack size Change of site of batch release Change of manufacturing site of assembly
•	22 August 2001	Change of distributor
•	17 March 2000	Change of MAH
•	30 November 1999	Addition of a manufacturer of the active substance
•	10 March 1998	Change of formulation
•	17 February 1998	Update of licence particulars
•	09 December 1997	Change of MAH