



## Post Authorisation Assessments

### Cephaguard DC 150mg Intramammary Ointment

Vm: 05653/5047

•	13 April 2024	Minor changes to the test procedure for assay and determination of impurities in the finished product.
•	12 June 2023	Change in the name of a manufacturer of the finished product. (NI)
•	15 December 2022	Change in the name of a manufacturer of the finished product. (GB)
•	18 March 2022	Deletion of manufacturing site for finished product.
•	10 December 2021	Addition of a manufacturer responsible for batch release including batch control/testing. Minor change in the manufacturing process of an immediate release solid oral dosage form. Change in storage conditions of the finished product. Addition of a manufacturing site of the finished product.
•	10 December 2021	Changes in the SPC, labelling or package leaflet following the outcome of a PSUR. Updates made to the SPC and QRD texts to align with the current QRD Template.
•	08 April 2021	Extension of a re-test period of the active substance.
•	06 April 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 June 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph. Deletion of a non-significant specification parameter of the finished product.
•	31 March 2013	Addition of a manufacturer of the active substance
•	27 July 2012	Minor change in manufacturing process of the finished product
•	18 July 2012	Additional batch size added
•	13 July 2012	Change to part of the packaging not in contact with the finished product formulation
•	15 March 2012	Minor change in the manufacture of the active substance
•	10 November 2011	Addition of a site of secondary assembly
•	26 April 2011	Deletion of a manufacturer of the active substance Change in test method performed on the active substance Update of the Active Substance Master File (ASMF)
•	26 January 2011	Approval of previously unseen mock ups
•	24 August 2010	Addition of pack sizes: Box of 6 sachets of 4 applicators and 24 cleaning towels Box of 30 sachets of 4 applicators and 120 cleaning towels

•	15 April 2010	Change of name of product in the RMS and all CMS's except UK and IE.
•	08 January 2010	Addition of a manufacturing site of the dosage form
•	21 December 2009	Renewal
•	29 October 2008	Change of MAH
•	12 August 2008	Change to batch release arrangements Addition of a site of secondary assembly
•	12 May 2008	Repeat use procedure
•	20 December 2006	Change of milk withdrawal period from 49 days to 35 days
•	03 November 2005	Change of distributor
•	21 September 2005	Addition of a manufacturer of the active substance