Veterinary Medicines Directorate

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Post Authorisation Assessments

Capstar 57 mg Tablets for Large Dogs

•	02 November 2021	Deletion of a non-significant parameter of an active substance. Deletion of a non-significant parameter of an active substance.
•	24 February 2021	Changes to the labelling and/or package leaflet.
•	28 January 2021	Replacement to a test procedure for the finished product.
•	09 September 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	16 March 2020	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	06 February 2020	Changes to the labelling and/or package leaflet.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	04 January 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	19 March 2018	Change in RMS from UK to FR.
•	16 August 2017	Changes to the labelling.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	15 February 2017	To amend section 4.6 of the SPC and the related text in the product literature.
•	08 November 2016	Change of MAH and Distributor, from Novartis Animal Health UK Limited to Elanco Europe Ltd.
•	15 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	28 June 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France only.
•	21 June 2016	Change in the name and address of the Marketing Authorisation Holder from Novartis Animal Health S.p.A to Elanco Italia S.p.A. in Italy only, and from Novartis Sanidad Animal, S.L. to Elanco Spain, S.L.U. in Spain only.
•	05 April 2016	Deletion of a non-significant in-process test applied during the manufacture of the finished product Extension of a re-test period of the active substance.

•	06 May 2014	To add/amend identification assays.
•	10 April 2014	Change in test procedures of the finished product and change of specification parameters for the finished product.
•	27 March 2014	Addition of pack size of 1 blister containing 1 tablet.
•	16 January 2014	Change of MA address in Portugal only.
•	10 October 2013	Change of manufacturer of the active substance.
•	04 July 2013	Change of MA holder address in France only.
•	28 March 2013	Change of MA holder address in Denmark, Finland, Norway and Sweden.
•	26 May 2011	Changes in the manufacturing process of the active substance Addition of a specification parameter of the active substance
•	07 September 2009	Change to Part II of the dossier
•	25 March 2009	Change in specification of the finished product
•	28 August 2008	Change in test procedure performed on the finished product
•	02 April 2008	Approval of unseen mock ups
•	20 December 2007	Increase of bulk holding time
•	28 September 2007	Renewal
•	03 September 2007	Change of address of the MAH
•	28 March 2007	Change of storage conditions
•	29 March 2006	Change of manufacturer of the active substance
•	12 March 2003	Change of legal category from POM to GSL
•	06 September 2002	Mutual Recognition procedure, UK as RMS