Veterinary Medicines Directorate

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Post Authorisation Assessments

Advocin 2.5% Solution for Injection

Vm 42058/4001

•	28 March 2022	Deletion of manufacturing site for an active substance. Extension of a re-test period of the active substance.
•	02 March 2022	Addition to a test procedure for an excipient.
•	01 April 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, First Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. Changes to the labelling and package leaflet.
•	08 January 2020	Replacement of a site for the manufacture of the active substance intermediate.
•	20 August 2019	Replacement or addition of a manufacturer responsible for batch release and batch control/testing. Replacement or addition of a secondary packaging site of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Decrease in batch size range of the finished product. Change to in-process tests applied during the manufacture of the finished product. Addition of a manufacturing site of the finished product.
•	08 August 2017	Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Changes to a test procedure (including replacement * or addition*) for the active substance. Change in the specification parameters and/or limits of the immediate packaging of the active substance. Additional manufacturer of the active substance only for synthesis.
•	19 December 2014	Change in the name of the manufacturer of the finished product, also responsible for batch release.
•	03 April 2014	Change of MAH, from Pfizer Ltd to Zoetis UK Limited. Change of distributor. Change in the address of an active substance manufacturer. Deletion of an active substance manufacturing site.
•	19 December 2011	Change in existing pharmacovigilance system as

		described in the DDPS.
•	02 September 2009	Variation to make changes to the specifications for the finished product and minor changes in test procedures for the finished product.
•	23 August 2007	Update of SPC in line with new legislation. Change in legal category from POM to POM-V. Addition of fluoroquinolones warning to the SPC.
•	11 May 2006	Renewal.
•	07 July 2005	Change of distributor.
•	28 February 2005	Change of manufacturer name/site.
•	26 September 2003	Renewal.
•	19 April 2002	Shelf life extended from 18 months to 24 months.
•	19 April 2002	Addition of a site for part of the manufacturing process for the active ingredient.
•	31 October 2001	Addition of a new therapeutic indication to the SPC.
•	20 April 2000	Use in additional species – pigs.
•	08 November 1999	Addition of a target species.
•	08 November 1999	Addition of a target species.
•	24 March 1998	Change in name/address of PL/ATC Holder.
•	20 June 1997	Change in manufacturer of active substance.
•	24 June 1996	Change in therapeutic indications.
•	24 June 1996	Change in shelf life.