Veterinary Medicines Directorate

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Post Authorisation Assessments

Combinex Oral Suspension

Vm 00879/4084

13 May 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
28 March 2025	Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product.
07 October 2024	Change in the specification parameters and limits of the immediate packaging of the finished product. Editorial changes to part 2 of the dossier.
07 October 2024	Change in the type of container closure. Change in the qualitative composition of the immediate packaging. Addition of a spigot cap administration device which is not an integral part of the immediate package. Change in the shape and dimensions of the immediate package. Change in the shape and dimensions of the container closure.
27 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
10 March 2023	New certificate of suitability from a new manufacturer.
17 November 2021	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.
25 August 2021	Change in the batch size of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
03 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
25 September 2020	Change in the address of the MAH 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.
12 August 2020	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Deletion of manufacturing site for an active substance.
15 August 2019	Introduction of a re-test period of the active substance. Submission of an updated Ph. Eur. certificate of

	suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
13 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
19 February 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
06 July 2017	Addition of a new specification parameter with its corresponding test method of the active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
07 March 2017	Introduction of a new pharmacovigilance system.
08 November 2016	Change of MAH and Distributor, from Novartis Animal Health UK Limited to Elanco Europe Ltd.
06 April 2016	Change in the manufacturer of the active substance
05 November 2015	Change of specifications of active substance to comply with the Ph.Eur.
20 June 2013	Update of sections 4.7 and 4.11 of the SPC.
24 August 2010	Change of name of manufacturer of the active substance.
30 June 2010	Addition of a safety warning regarding mixing with other products.
03 November 2009	Changes to the layout of the product literature.
25 January 2009	Change of name of manufacturer of the active substance.
23 April 2008	Changes to the SPC and Product Literature to bring in line with new legislation.
12 December 2007	Change of MAH address.
03 May 2006	Addition of new pack sizes – 12L and 21L.
19 April 2006	Renewal.
07 March 2006	Change of legal category from PML to POM-VPS.
22 February 2006	Change to Part II of the Dossier.
12 May 2005	Addition of a manufacturer of the dosage form.
20 April 2005	Deletion of manufacturer of the dosage form.
28 November 2003	Renewal.
29 July 2003	Update of Active Substance Master File (ASMF).
11 July 2003	Addition of a manufacturer of the active substance.

15 December 1999	Change of manufacturer of the active substance.
22 March 1999	Change of manufacturer of the dosage form.
28 November 1997	Renewal.
24 April 1997	Change of size of sterile containers.
01 October 1996	Change of type of sterile containers.
14 March 1996	Change to dosage particulars.