

Post Authorisation Assessments

Combinex Cattle Oral Suspension

Vm 00879/4083

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| 23 September 2025 | Submission of a Ph. Eur. CEP for and active substance. |
| 13 May 2025 | Change in immediate packaging of the finished product. Change in immediate packaging of the finished product: qualitative and quantitative composition. Change of administration device. Change in shape and dimensions of the container closure immediate packaging. Change in shape and dimensions of the container closure immediate packaging. |
| 13 May 2025 | Change in the specification parameters and limits of the immediate packaging of the finished product. Editorial changes to part 2 of the dossier. |
| 23 April 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. |
| 20 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. |
| 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 |

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| | 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. |
| 04 October 2016 | Change in batch size of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. |
| 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 |
| 26 April 2011 | Change in composition of the finished product |
| 24 August 2010 | Deletion of a manufacturing site of an active substance Change of name of manufacturer of an active substance |
| 03 November 2009 | Changes to the layout of the product literature |
| 25 January 2009 | Change of name of manufacturer of the active substance |
| 11 June 2008 | Changes to the SPC and Product Literature to bring in line with new legislation |
| 12 December 2007 | Change of MAH address Change of distributor address |
| 03 May 2006 | Addition of 2 pack sizes – 12L and 21L |
| 22 February 2006 | Update to Part II of the Dossier |
| 13 February 2006 | Change of legal category from PML to POM-VPS |
| 02 February 2006 | Renewal |
| 12 May 2005 | Addition of manufacturer of the dosage form |
| 20 April 2005 | Deletion of a manufacturing site of the dosage form |
| 21 January 2005 | Increase of withdrawal period for meat to 56 days Renewal |
| 29 July 2003 | Update of Active Substance Master File (ASMF) |
| 11 July 2003 | Addition of a new manufacturer of an active substance |
| 15 December 1999 | Change of manufacturer of an active substance |
| 22 March 1999 | Change of manufacturer of the dosage form |
| 17 June 1997 | Renewal |
| 24 April 1997 | Change in size of sterile containers |
| 15 March 1996 | Change in dosage particulars |