Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Paracox-8, Suspension for Oral Suspension for Chickens

Vm 06376/3044

10 March 2025	Change of Marketing Authorisation Holder from: MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to: Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
19 January 2025	Deletion of finished produce batch release site.
20 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
25 July 2023	Change in the address of a quality control testing site.
27 July 2022	To change the approved specification limit for the pH of the solvent.
18 February 2022	Deletion of a method of administration of the finished product.
27 October 2021	Change in the invented name of the veterinary medicinal product from Paracox, Suspension for Oral Suspension for Chickens to Paracox-8, Suspension for Oral Suspension for Chickens.
13 July 2021	Change in distributor details. From various addresses to Same as MAH, Alternative distributor in Northern Ireland, Intervet Ireland Limited, Magna Drive, Magna Business Park, Citywest Road, Dublin 24.
02 July 2021	Deletion of a non-significant specification parameter of the finished product. Change in the fill volume of the finished product. Change to a test procedure for the finished product. Change to a test procedure for the finished product. Change to a test procedure for the finished product. Addition of a test procedure for the finished product. Change to a test procedure for the finished product. Increase in the shelf-life of the finished product as packaged for sale, from 28 weeks to 33 weeks. Change in type of container for the finished product. Changes in the manufacturing process of the finished product.
20 May 2021	Addition of a site where batch control/testing takes place.
01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
14 August 2020	Replacement of a site where batch control/testing takes place.
02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire,

	MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
15 April 2019	Addition of a manufacturer responsible for batch release.
30 October 2018	Increase in the shelf-life of the finished product as packaged for sale, from 15 months to 24 months.
03 August 2018	Change in manufacturer of active substance. Change in quality control and batch release site. Change in manufacturing site of finished product.
12 April 2018	Change in the SPC, labelling or package leaflet due to new data. Change in the composition (excipients) of the finished product.
23 June 2016	Change in the manufacturing process of the active substance.
19 November 2015	Changes in the manufacturing process of the active substance
06 November 2014	Change in the manufacturing process of two active substances.
20 January 2014	Changes in the manufacturing process of the active substance.
17 November 2011	Change in the manufacturing process of an active substance and some editorial changes to the dossier.
26 April 2011	Change of MAH from Schering Plough Ltd to Intervet UK Ltd.
07 July 2010	Change of legal category from POM-V to POM-VPS.
15 July 2009	Alignment variation.
03 December 2008	Revision of the seed lot system.
27 February 2007	Addition of hatchery spray as further method for oral administration.
17 August 2006	Renewal
14 January 2002	Change to ‘Special precautions for use’ on the SPC.
17 January 2000	Change in the method of manufacture.
05 January 2000	Update to licence particulars.
05 January 2000	Change to the manufacturing process.
05 January 1999	Change to the shelf-life of the finished product.