Veterinary Medicines Directorate

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Post Authorisation Assessments

Paracox-5, Suspension for Oral Suspension for Chickens

Vm 01708/5101

11 December 2024	Correction of Package Leaflet section 7 endnotes under table.
11 December 2024	Deletion of a site where batch control takes place
27 June 2024	G.I.18 update to SPC and QRD.
19 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
30 August 2023	Increase of the finished product batch size.
27 July 2022	To change the approved specification limit for the pH of the solvent.
01 December 2021	Change in the address of a quality control testing site. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Addition to a test procedure for 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.
14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
24 January 2019	Addition of a manufacturer responsible for batch release of the finished product.
08 November 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.
01 May 2018	Change in RMS from UK to FR.
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.
06 November 2014	Change in the manufacturing process of two active substances.
21 August 2014	Approval of mock-ups following a minor correction and layout change. Addition of a distributor for Northern Ireland.
16 April 2014	Change in name and/or address details of the manufacturer of the active substance and change in name and/or address details of the manufacturer of the finished product.
20 January 2014	Change in the manufacturing process of the active substance.
17 November 2013	Change in the manufacturing process of the active substance.
04 August 2011	Variation to change the name of the Marketing Authorisation Holder in Portugal.

05 August 2010	Renewal (UK as RMS).
26 May 2010	Variation to change the legal category from POM-V to POM-VPS.
08 April 2010	Variation to change the Marketing Authorisation Holder.
14 August 2009	Change of name and address of the Marketing Authorisation Holder in France.
19 November 2008	To revise seed lot system.
07 December 2006	Change of name and address of the Marketing Authorisation Holder.
28 September 2001	Route of administration.
28 September 2001	Route of administration.
12 July 2000	Change to shelf-life.