Veterinary Medicines Directorate

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

Post Authorisation Assessments

Cevac Salmovac Lyophilisate for Use in Drinking Water

Vm 15052/3012

•	08 December 2023	To include more specific definitions of the tests that can be used to distinguish the vaccine strain from wild-type strains and to introduce an alternative differentiation test. One-off alignment of the product information with version 9.0* of the QRD templates.
•	23 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	25 March 2022	Update of the product literature and packaging to harmonise the product information between old and new member states and in line with QRD template v8.2.
•	25 March 2022	Change in the invented name of the veterinary medicinal product from Salmovac 440 to Cevac Salmovac.
•	29 July 2021	Repeat Use application to add 8 new member states.
•	08 March 2021	Introduction of a new pharmacovigilance system.
•	19 January 2021	Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	06 October 2020	Change of MAH, from IDT Biologika GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany to Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB, United Kingdom.
•	17 April 2020	Change in the specification parameters and/or limits used in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	28 August 2019	Change in the invented name of the veterinary medicinal product from Gallivac SE to Salmovac 440. Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Update to the QRD.
•	16 March 2018	Introduction of a new pharmacovigilance system.
•	19 December 2017	Minor changes to an approved test procedure of the

		finished product.
•	14 December 2016	Change of MAH, from Merial Animal Health Limited to IDT Biologika GmbH
•	25 November 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	21 March 2014	Change in the MAH address in Spain and Portugal only
•	05 July 2013	Repeat use Comm
•	06 April 2011	Addition of indication for protection against *Salmonella enteritidis* and *Salmonella typhimurium* infection Updates to the SPC and Product Literature
•	08 November 2010	Changes of test procedures performed on the finished product Deletion of a specification parameter
•	19 February 2008	Harmonisation of the Product Literature Change of name and address of manufacturer of the finished product
•	21 December 2007	Repeat use Comm Renewal
•	07 March 2007	Change of legal category from POM to POM-V
•	05 December 2003	Change of address of the MAH in France only