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 15052/5045

25 February 2025	Change in the shelf-life specification – deletion of parameters which are not stability indicating. Deletion of in-process tests, which have no impact on the overall quality of the product. Addition of alternative manufacturers for yeast and peptone. Addition of a manufacturing and control testing site including minor changes to the manufacturing process, batch size and in process controls. Addition of Ceva-Phylaxia as site where batch control testing takes place including test methods transfer. Addition of a finished product manufacturing site including minor changes to the manufacturing process, batch size and in process controls to adapt to the new manufacturing site settings (immunological product).
20 July 2024	Change in the name of a qualified person for pharmacovigilance (QPPV).
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