



Post Authorisation Assessments

Entericolix, Emulsion for Injection for Pigs Vm 30824/4003

•	31 January 2024	Addition of a secondary packaging site of a finished product. (GB)
•	29 August 2023	Added to SPC and QRD AE: Anaphylactic reactions have been reported very rarely.
•	09 March 2023	Change in name and address of the manufacturer of the finished product. Change in name and address of the manufacturer of the active substance. Change in name and address of the marketing authorisation holder from CZ Veterinaria, S.A., La Relva s/n- Torneiros, 36410 Porriño (Spain) to CZ Vaccines S.A.U., A Relva s/n – Torneiros, 36410 O Porriño, Pontevedra, Spain.
•	21 February 2023	To increase the maximum acceptable titre of the active substance from the current authorised titre of $\leq 8.9 \times 10^{10}$ cfu/mL to the new limit of $\leq 1.2 \times 10^{11}$ cfu/mL.
•	17 November 2020	Renewal - UK as CMS.
•	08 March 2019	Change in distributor details from Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	18 December 2018	Change of the local representative in the United Kingdom to Boehringer Ingelheim Animal Health UK Ltd.
•	15 December 2016	Increase in the shelf-life of the finished product, from 1 year to 2 years.
•	21 November 2016	Change in Distributor details from CZ Veterinaria, S.A. to Boehringer Ingelheim Ltd.