



## Post Authorisation Assessments

### Entericolix, Emulsion for Injection for Pigs Vm 30824/4003

|   |                  |                                                                                                                                                                                                                                                                                                                                                                                      |
|---|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| • | 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.<br>Change in name and address of the manufacturer of the active substance.<br>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.                                                                                                                                                                                                                                                                                                 |