



## Post Authorisation Assessments

### Enzaprost 5 mg/ml Solution for Injection for Cattle and Pig

Vm 14966/3036

16 May 2026	Minor change to comply with an updated monograph of the Ph. Eur.
16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. Change in the pharmacovigilance system master file (PSMF) location.
05 March 2026	Submission of updated mock ups.
03 October 2025	Change in the Marketing Authorisation Holder from Ceva Animal Health Ltd to Ceva Sante Animale.
01 September 2025	Alignment of the product information with version 9.0* of the QRD templates.
12 June 2024	Changes in the manufacturing process of the active substance.
25 January 2024	Change in name of the manufacturer of the active substance. Change in name of ASMF holder. (NI)
13 January 2023	Change in name of the manufacturer of the active substance. Change in name of ASMF holder. (GB)
22 September 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
09 December 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
29 May 2020	Update to ASMF.
10 December 2019	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
30 July 2019	Update to the product literature.
20 February 2019	Repeat Use application to add 5 new member states
07 February 2019	Change in RMS from UK to FR
29 March 2018	To update the SPC and QRD text following an MRP Repeat-Use Renewal
29 November 2017	Renewal UK as RMS
19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
19 September 2017	Change in the name and/or address of the MAH in Spain only.
21 December 2016	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Change in the limits of relative density.

22 December 2015	Updating of the DDPS system.
23 April 2015	Changes in the manufacturing process of the active substance.
11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
13 July 2012	Repeat use.
05 January 2012	Change of name of MAH.
11 October 2011	Change of MAH address.
12 August 2011	Introduction of a new pharmacovigilance system.
18 June 2009	Renewal.
12 March 2008	Change of product name in Austria only.
08 February 2008	Change of MAH address in Portugal.
15 December 2005	Change of MAH address in Spain and Belgium.
23 December 2004	Change of product name in Portugal only.
26 November 2003	Mutual recognition procedure, UK as RMS.
02 January 2003	Change of address of MAH.
30 September 2002	Updates to the Dossier.
27 June 2002	Addition of a 50ml pack size.