



Post Authorisation Assessments

Cronyxin Injection 50 mg/ml Solution for Injection Vm 50146/4011

May 2026	One-off alignment of the product information with version 3 of the QRD template.
18 September 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
10 November 2023	Deletion of a manufacturer of the active substance authorised via Ph. Eur. CEP. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance.
11 October 2023	Replacement of a secondary packaging site of the finished product.
11 October 2023	Minor change in the manufacturing process of the finished product. Replacement of a manufacturing site responsible for batch control and batch release of the finished product. Replacement of a manufacturing site responsible for all of the manufacturing process of the finished product.
18 March 2021	Replacement of a secondary packaging site of the finished product.
26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
29 June 2020	Changes to a test procedure for the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form. Replacement of an excipient with a comparable excipient.
03 March 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
23 July 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
24 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
10 May 2018	Submission of an updated Ph. Eur. certificate of

	suitability for an active substance from an already approved manufacturer.
15 January 2015	Deletion of a Ph. Eur. certificate of suitability. Replacement of a Ph. Eur. certificate of suitability with a new manufacturer.
06 May 2015	Submission of an updated certificate of suitability.
09 July 2013	Approval of previously unseen mock ups
15 February 2012	Change of immediate packaging container type Change in batch size Change of in-process specifications of the finished product Change of finished product specification Submission of an updated Ph. Eur. Certificate of Suitability Addition of a manufacturer responsible for batch release
11 April 2011	Addition of a manufacturer of an active substance
23 December 2010	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
27 November 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
17 November 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
13 November 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
28 August 2008	Corrections to the SPC and Product Literature
13 February 2006	Renewal
14 December 2005	Addition of new user warnings to the SPC and Product Literature
04 November 2004	Change to the SPC to bring in line with new legislation
16 May 2003	Addition of a manufacturer of the dosage form
16 August 2002	Addition of a manufacturer of the active substance
07 November 2001	Change of manufacturer of the dosage form
24 July 2001	Renewal
13 April 1999	Change of type of sterile container
23 October 1998	Change of finished product specification
24 September 1997	Change of manufacturing site of the dosage form