



Post Authorisation Assessments

Regulin 18 mg Implant

Vm 14966/5017

30 September 2025	Change in legal entity of MA holder from Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom to Ceva Sante Animale, 8 rue de Logrono, 33500 Libourne, France.
09 May 2025	Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for an active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
09 May 2025	Addition of a test procedure for the active substance.
05 September 2024	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
03 October 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.
03 February 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging).
16 April 2020	Addition of a manufacturing site of the finished product.
12 June 2019	Addition of a manufacturer of the active substance or addition of a site of manufacture.
05 April 2018	Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product. Change in the specification of the finished product.
07 February 2017	Minor change to the restricted part of an Active Substance Master File.
30 March 2015	Change in batch size of the active substance.
03 April 2012	Replacement of a manufacturer of the active substance supported by an ASMF.
23 September 2011	Change in address of MAH.
13 December 2007	Changes to the SPC and product literature to bring them into line with new legislation.
21 June 2007	Renewal.
27 May 2004	Change to the packaging.
11 March 2004	Renewal.
25 July 2003	Change of manufacturer address.

16 May 2003	Change of legal category.
25 April 2003	Change of manufacturer and assembler of the finished product.
25 April 2003	Change in manufacture of product.
31 January 2003	Change of packaging shape.
02 January 2003	Change of address of MAH.
05 January 2001	Change of address of MAH.
08 February 1999	Change to packaging.
04 February 1999	Renewal.
08 January 1998	Change of MAH.
30 April 1997	Additional distributor.