



## Post Authorisation Assessments

### Regulin 18 mg Implant Vm 15052/4011

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| • | 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.<br>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.<br>Deletion of a non-significant specification parameter of the finished product.<br>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.  |

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| • | 30 April 1997 | Additional distributor. |
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