

## **Post Authorisation Assessments**

## Euthatal Solution for Injection 200 mg in 1ml Vm 28365/4015

|   | 17 December 2010    | Introduction of a new phormacovicilance evotom  |
|---|---------------------|---|
| • | 17 December 2019    | Introduction of a new pharmacovigilance system.   |
| • | 19 September 2019   | Change in the name of a manufacturer of the finished  |
|   |                     | product, also responsible for batch release.  |
| • | 04 September 2019   | Change of distributor from: Boehringer Ingelheim Animal   |
|   |                     | Health UK Limited to Duggan Veterinary Supplies   |
|   |                     | Limited.  |
| • | 09 August 2019      | Change in MAH from: Boehringer Ingelheim Animal   |
|   |                     | Health UK Ltd   |
|   |                     | Ellesfield Avenue<br>Bracknell  |
|   |                     | Berkshire   |
|   |                     | RG12 8YS  |
|   |                     | to:   |
|   |                     | Dopharma Research B.V.  |
|   |                     | Zalmweg 24  |
|   |                     | 4941 VX Raamsdonksveer  |
|   | 00 Nevremeh en 0040 | The Netherlands   |
| • | 29 November 2018    | Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, |
|   |                     | Sandringham House, Sandringham Avenue, Harlow   |
|   |                     | Business Park, Harlow, Essex, CM19 5TG to Boehringer  |
|   |                     | Ingelheim Animal Health UK Ltd, Ellesfield Avenue,  |
|   |                     | Bracknell, Berkshire, RG12 8YS.   |
| • | 20 May 2015         | Change in name of manufacturer for secondary  |
|   |                     | packaging, batch control and batch release.   |
| • | 04 September 2014   | Replacement of the manufacturer of the bulk solution  |
|   |                     | and primary packaging site.<br>Increase of batch size.  |
| • | 11 March 2010       | Change of manufacturer responsible for batch release.   |
| • | 18 March 2008       | Renewal.  |
| • | 16 November 2006    | Changes to the SPC and Product Literature to bring in   |
|   |                     | line with new legislation.  |
| • | 13 October 2005     | Renewal.  |
| • | 19 June 2003        | Change of shape of packaging.   |
| • | 24 September 2002   | Change of manufacturer of the active substance.   |
| • | 22 January 2002     | Change of shelf life from 24 to 36 months.  |
| • | 22 January 2002     | Change of formulation.  |
| • | 19 December 2001    | Change of manufacturing process of the finished   |
| 1 |                     |   |
|   | 11 July 2001        | product.<br>Harmonisation of the SPC.   |

| • | 21 July 1999     | Renewal.  |
|---|------------------|---|
| • | 02 February 1999 | Change of type of sterile containers.                         |
| • | 29 June 1998     | Change of MAH.  |
| • | 09 October 1997  | Change to manufacturer of the active substance.               |
| • | 02 May 1995      | Change of manufacturing site of assembly for the dosage form. |