



## Post Authorisation Assessments

### Dexadreson 2mg/ml Solution for Injection Vm 01708/4323

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| • | 20 December 2022  | Updated certificate of suitability from an already approved manufacturer.   |
| • | 15 March 2022     | Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.   |
| • | 28 April 2021     | Change in name of the MAH from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ. |
| • | 24 April 2018     | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.   |
| • | 09 August 2017    | Deletion of manufacturing site for an active substance. To update section 4.6 of the SPC to include the phrase: In very rare cases hypersensitivity reactions might occur.                                    |
| • | 11 December 2015  | Submission of an updated certificate of suitability.  |
| • | 04 December 2013  | Changes to the SPC and product literature as a result of an EU Directive.   |
| • | 08 February 2013  | Submission of an updated Ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer   |
| • | 16 August 2012    | Change of shelf life from 5 years to 3 years  |
| • | 05 March 2009     | Change of specification of the finished product   |
| • | 25 June 2008      | Change of legal category from POM to POM-V<br>Changes to the SPC and Product Literature to bring in line with new legislation   |
| • | 11 June 2008      | Submission of a new Ph. Eur. Certificate of Suitability for the active substance<br>Change of manufacturer of the active substance  |
| • | 09 February 2006  | Renewal   |
| • | 02 February 2006  | Change of distributor   |
| • | 08 April 2004     | Change of withdrawal periods<br>Milk from 72 hours to 60 hours<br>Meat from pigs from 21 days to 2 days<br>Meat from cattle from 21 days to 7 days  |
| • | 20 October 2003   | Renewal   |
| • | 18 September 2003 | Change of shelf life from 24 months to 5 years  |
| • | 11 April 2003     | Addition of a manufacturer and site of batch release  |
| • | 03 July 2001      | Change of distributor   |
| • | 27 June 2000      | Update of licence particulars   |

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| • | 18 November 1997 | Change of shelf life |
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