



Post Authorisation Assessments

Dexadreson 2mg/ml Solution for Injection

•	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 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 Change of manufacturer of the active substance
•	09 February 2006	Renewal
•	02 February 2006	Change of distributor
•	08 April 2004	Change of withdrawal periods Milk from 72 hours to 60 hours Meat from pigs from 21 days to 2 days 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
•	18 November 1997	Change of shelf life