Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovarelin 50 µg/ml, Solution for Injection for Cattle

Vm 15052/5058

•	19 December 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	19 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	04 May 2024	Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance: - Other changes
•	05 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH, United Kingdom.
•	06 March 2020	Modification to the manufacturing process of the finished product.
•	22 August 2019	Minor change in the manufacturing process of an immediate release oral solutions. Change to in-process tests applied during manufacture of finished product.
•	11 July 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	18 April 2019	Change in the invented name of the veterinary medicinal product from Ovarelin 50 µg/ml, solution for injection for cattle to Ovareline 50 µg/ml, solution for injection for cattle in Norway. Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products
•	19 February 2019	Change of RMS from UK to IE.
•	30 October 2018	Repeat use application to add 4 new member states.
•	29 March 2018	Updates to the SPC and PL following a repeat use procedure.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	30 August 2017	Renewal – UK as RMS.
•	07 November 2016	Approval of mock ups for the 20 ml presentation.
•	15 March 2016	Addition of a new therapeutic indication and modification of an approved indication.

•	22 December 2015	Updating of the DDPS system.
•	06 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	15 January 2015	Change in the address of the MAH in Czech Republic only.
•	17 August 2012	Repeat Use procedure.
•	06 January 2012	Change in the name and/or address of the Marketing Authorisation Holder.
•	01 December 2011	Renewal – UK as RMS.
•	16 December 2010	To change the medicinal product name in Spain.
•	13 January 2010	To change the manufacturing site for the active substance of the approved manufacturer.