

Veterinary Medicines Directorate Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

Zeleris 400 mg/ml + 5 mg/ml Solution for Injection for Cattle Vm 15052/5026

21 February 2025	Substantial changes in the updated version of the ASMF for florfenicol.
24 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
08 August 2023	Updated indication with the addition of Mycoplasma bovis and associated warnings: For therapeutic treatment of bovine respiratory disease (BRD) due to Histophilus somni, Mannheimia haemolytica, Pasteurella multocida and Mycoplasma bovis associated with pyrexia. One-off alignment of the product information with version 9.0* of the QRD template.
28 November 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials. Addition of manufacturing site responsible for radiosterilisation of plastic vials.
19 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.
28 April 2022	Renewal.
20 December 2021	Updates to the ASMF.