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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

• 08 Au	ugust 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 No	ovember 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials. Addition of manufacturing site responsible for radiosterilisation of plastic vials.
• 19 00	ctober 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 Ap	oril 2022	Renewal.
• 20 De	ecember 2021	Updates to the ASMF.