Veterinary Medicines Directorate
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Post Authorisation Assessments

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

Zactran 150 mg/ml Solution for Injection for Cattle, Sheep and Pigs

Vm 04491/5061

	04 September 2024	Change in any part of the primary packaging material not in contact with the finished product formulation. Change in dimensions of the closure on the immediate packaging. Change in dimensions of the immediate packaging of the finished product. Minor change in test procedure for an excipient. Minor change in test procedure for an excipient. Minor change in test procedure for an excipient. Minor change in test procedure for the finished product. Minor change in test procedure for the finished product. Minor change in test procedure for the finished product. Change in the specification parameters and limits of the finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	12 June 2024	Addition of a manufacturer responsible for batch control arrangements and quality testing of the finished product. Addition of a manufacturer responsible for batch control arrangements and quality testing of the finished product. Addition of a manufacturer responsible for batch control arrangements and quality testing of the finished product. Addition of a manufacturer responsible for batch release including batch control or testing of the finished product. Addition of a secondary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	12 June 2024	Minor changes to an approved test procedure for an active substance. Minor changes to an approved test procedure for an active substance.
•	12 June 2024	Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an active substance.
•	19 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	26 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	26 April 2023	Deletion of a manufacturer of the active substance.

•	15 February 2022	Changes to the labelling and/or package leaflet.
•	19 January 2022	Change in the name/address of starting material used in the manufacture of the active substance.
•	25 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	01 March 2021	Change in the SPC, labelling or package leaflet due to new data.