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.

Arti-Cell Forte Suspension for Injection for Horses

Vm 04491/5062

	13 April 2024	Minor modifications in test procedure for the finished product. Minor change in the manufacturing process of the finished product.
•	11 January 2024	Increase clarity of donor horse management: eliminating redundancies, clarifying roles and responsibilities, and details of documentation required.
•	06 October 2023	Unlimited renewal.
•	11 August 2023	Extension of the storage period of active substance. Extension of the finished product shelf life.
•	12 April 2023	Changes in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	25 October 2022	To update information on the manufacturing process of the active substance.
•	12 October 2022	Minor changes to an approved change management protocol of the active substance that does not change the strategy defined in the protocol.
•	31 August 2022	Update to product labelling for a name change of a manufacturer responsible for batch release.
•	12 April 2022	Change to an approved stability protocol.
•	24 November 2021	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	24 November 2021	Introduction of a new pharmacovigilance system.
•	07 July 2021	Change of MAH, from Global Stem cell Technology NV, Noorwegenstraat 4, 9940 Evergem, Belgium to Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.
•	04 June 2021	Extension of a storage period of the active substance. Change to an approved stability protocol.