



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

	14 May 2024	Minor changes in the manufacturing process of the active substance.
	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.