Veterinary Medicines Directorate

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Post Authorisation Assessments

Gleptosil 200 mg/ml Solution for Injection

Vm 15052/4079

•	06 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.
•	29 June 2022	Change in radiosterilisation dose range for vial stoppers for new site. Addition of new radiosterilisation site for plastic vials. Addition of new radiosterilisation site for vial stoppers.
•	17 January 2022	Additional supplier of starting material for the manufacture of the active substance.
•	21 May 2020	Minor changes to an approved test procedure of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
•	15 January 2020	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years for 100 ml and 250 ml CLAS vials.
•	26 July 2018	Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Increase in batch size of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form. Tightening of specification limits of the finished product. Addition of a manufacturing site of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Addition of a new container for the finished product. Change in the fill volume of the finished product.
•	23 August 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 June 2016	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance.

		Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant specification parameter of the finished product. Replacement of a manufacturing site of the finished product. Addition of a manufacturer of the active substance. Widening the limits for specified parameters on the active substance specification
•	16 December 2015	Changes to update the DDPS System.
•	20 August 2015	Change to the distributor. Approval of mock-ups.
•	08 June 2015	Introduction of a new pharmacovigilance system.
•	03 June 2015	Change of MA holder from Sogeval UK Ltd to Ceva Animal Health Ltd.
•	20 May 2014	Change of finished product manufacturing site responsible for primary and secondary packaging, quality control and batch release.
•	17 April 2014	Change of MA holder from Alstoe Limited to Sogeval UK Ltd.
•	21 December 2009	Change of tests performed on the finished product
•	27 May 2009	Harmonisation of the SPC
•	16 December 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	02 November 2007	Change of composition of the packaging of the 100ml presentation
•	08 February 2006	Renewal
•	22 January 2004	Minor change in the manufacture of the finished product
•	26 June 2003	Change to test procedure performed on the active substance
•	26 October 2001	Change of address of the MAH
•	02 March 2001	Renewal
•	10 November 1998	Change of name and address of the MAH
•	14 June 1996	Change of manufacturer and assembler of the dosage form