Veterinary Medicines Directorate

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Post Authorisation Assessments

Ferroferon 200 mg/ml Solution for Injection for Pigs

Vm 20631/4002

•	30 November 2023	Change in legal entity of MA holder from Iron4u ApS, Naesseslottet, Dronninggårds Allé 136, DK-2840 Holte, Denmark to Serumwerk Bernburg AG, Hallesche Landstraße 105 b, D-06406 Bernburg, Germany.
•	15 June 2021	Introduction of a new pharmacovigilance system.
•	05 February 2021	Replacement of a manufacturer responsible for batch release of the finished product.
•	17 May 2019	Introduction of a new pharmacovigilance system
•	09 May 2019	Change in the specification parameters of the finished product.
•	06 November 2018	Addition of a batch release site of the finished product – AT only. Change in the invented name of the veterinary medicinal product from Ursoferran 200 mg/ml to Gleptosil 200 mg/ml – AT only.
•	27 April 2018	Change in the invented name of the veterinary medicinal product from 'Prolongal 200 mg/ml' to 'Ursoferran 200 mg/ml' in AT, BE, CZ, FR, IT, LU, PL, and SK.
•	05 December 2017	Renewal UK as CMS
•	07 July 2017	Change in the fill volume of the finished product.
•	22 February 2017	To introduce a new material for secondary packaging.
•	02 February 2017	Change in the specification limits of the finished product.
•	18 October 2016	Introduction a new supplier for the LDPE-bottle.
•	06 July 2016	Change in the QPPV details which does not affect the UK.
•	22 June 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	13 January 2016	To update the Part II.C data for the active substance.
•	08 December 2015	Introduction of a new pharmacovigilance system
•	12 December 2014	Update to the pharmacovigilance system.
•	20 August 2014	Change of distributor.
•	22 May 2014	To change the batch size of the active substance. To change the specification parameters of the active substance.
•	14 May 2014	To change the name of the MAH in France, from ‘Bayer Santé’ to ‘Bayer Healthcare’.
•	09 May 2014	Change to the manufacturing process of the active substance. Changes to in-process tests and specification parameters.

		Change to the test procedures. Addition of a supplier.
•	14 April 2014	Change in the manufacture responsible for batch release in Hungary, Spain and the UK.
•	29 November 2013	Change in MAH. Change of legal category from POM-V to POM-VPS.
•	01 November 2013	Change in the invented name of the product, from ‘Ursoferran 200 mg/ml’ to ‘Ferroferon 200 mg/ml’.
•	30 May 2013	Updated SPC and Product Literature to include hypersensitivity warning after repeat use procedure.
•	20 March 2013	Repeat Use Comment.