Veterinary Medicines Directorate

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Post Authorisation Assessments

Ferroferon 200 mg/ml Solution for Injection for Pigs

Vm 20631/5001

04 March 2025	One-off alignment of the product information with version 3 (V3) of the QRD template.
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.