Veterinary Medicines Directorate

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Post Authorisation Assessments

Itrafungol 10 mg/ml Oral Solution

Vm 05653/3007

•	25 May 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	09 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 November 2021	Changes to the labelling and/or package leaflet.
•	13 July 2021	Change of Marketing Authorisation Holder from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to VIRBAC, 1ère avenue 2065m LID, 06516 Carros, France. Change of Distributor from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Virbac Limited, Unit 16 Woolpit Business Park, Windmill Avenue, Bury St Edmunds, Suffolk IP30 9UP.
•	03 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	01 October 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 February 2018	Change in the RMS from UK to IE.
•	13 January 2016	To replace the batch release and testing site. To delete the active substance manufacturer. Replacement of a secondary packaging site of the finished product. Replacement of a primary packaging site of the finished product. Submission of a new or updated Ph. Eur. certificate of suitability Change in test procedure for an excipient. To replace the site of finished product manufacture.
•	07 January 2016	To make three minor changes to the manufacture of the finished product.

		Addition of a retest period of 48 months for the active substance.
•	30 September 2015	Approval of new mock-ups.
•	08 May 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
•	03 April 2014	Changes to an existing pharmacovigilance system.
•	07 November 2013	Change of address of the MAH in Portugal
•	13 June 2013	Change of address of the MAH
•	09 November 2012	Change of composition of excipients
•	08 August 2012	Change of MAH
•	07 March 2012	Change of distributor details
•	11 August 2011	Change of batch size Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	03 June 2011	Changes to an existing pharmacovigilance system as described in the DDPS
•	24 February 2011	Change of test procedures performed on an excipient Change of specifications of excipients
•	28 April 2010	Change of address of the MAH
•	12 March 2010	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance
•	05 February 2010	Renewal
•	01 May 2009	Change of address of the MAH in Germany
•	18 December 2008	Change to test method performed on the finished product
•	09 October 2008	Addition of a new test parameter for the finished product specification
•	08 May 2008	Change to dosing device
•	22 April 2008	Changes to the Product Literature for a dosing device
•	07 March 2008	Change of address of the MAH
•	28 March 2007	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	10 January 2006	Change of in-process control methods performed during the manufacture of the finished product
•	26 May 2005	Change to specification of an excipient Addition of a manufacturer of the active substance
•	05 January 2005	Mutual Recognition Procedure, UK as RMS
•	16 May 2003	Change to specification of an excipient Change to test method performed on the immediate packaging