Veterinary Medicines Directorate

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Post Authorisation Assessments

Atopica 100 mg Soft Capsules for Dogs

Vm 00879/3012

•	25 March 2024	Tightening of specification limits of an intermediate. Tightening of specification limits of an intermediate. Tightening of specification limits of an intermediate. Tightening of specification limits of an intermediate.
•	08 December 2023	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State:– change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	23 June 2023	Pharmacovigilance sections updated to align product.
•	23 June 2023	One-off alignment of the product information with version 9.0* of the QRD template.
•	05 December 2022	Introduction of a re-test period for a new active substance manufacturer source.
•	08 March 2022	Change in the name of a manufacturer used in the manufacture of the active substance.
•	08 July 2021	Change in the name and address of a manufacturer of the active substance.
•	09 June 2021	Change in the specification parameters and/or limits of an excipient. Change in the specification parameters and/or limits of an excipient.
•	25 September 2020	Change in the address of the MAH from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood, Business Park, Hook, RG27 9XA, United Kingdom.
•	25 March 2020	Change in the specification parameters and/or limits of an active substance, used in the manufacturing process of the active substance. Removal of non-significant test parameter from the raw material specifications. Minor change to the restricted part of an Active Substance Master File.
•	30 August 2019	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance.
•	17 June 2019	Change in source of an excipient or reagent with TSE risk
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 May 2019	Tightening of specification limits of an excipient

•	07 March 2017	Introduction of a new pharmacovigilance system.
•	30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
•	15 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	06 July 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France and Poland only.
•	06 July 2016	Change in the name and address of the Marketing Authorisation Holder in Spain and Italy only.
•	25 November 2015	Widening of specification limits. Changes in the manufacturing process of the active substance. Deletion of a manufacturer of the active substance. Tightening of specification limits. Addition of an identification test. Deletion of tests from raw material specifications.
•	31 July 2015	Grouped variation to change the name of the bulk manufacturer, replacement of sites for both batch release and Microbial tests and the deletion of both a manufacturing site and a packaging site.
•	07 October 2014	Update to the text in Section 4.5 and 4.9 on the SPC and the relevant sections of the product literature.
•	07 February 2014	Change to the address of the MAH in Portugal only.
•	15 January 2014	Changes to test procedures for the active substance and intermediate used in the manufacturing process of the active substance. Changes to the specification limits of the active substance and of the intermediate used in the manufacturing process of the active substance.
•	15 October 2013	Changes to the specification limits of the finished product. Minor changes to the test procedures for the finished product.
•	05 July 2013	To change the address of the MAH in France only.
•	28 March 2013	To change the address of the MAH in Denmark, Finland, Norway and Sweden and corrections to the address of the MAH in Cyprus.
•	27 February 2013	To update the SPC and product literature text and to change the ATCVet code.
•	01 July 2008	Change to the markings of the finished product.
•	29 May 2008	Renewal.
•	09 October 2007	To change the address of the marketing authorisation holder (MAH) and distributor.
•	20 July 2006	Addition of new packaging sites, to change the pack size of the finished product and to change the dimensions of the immediate packaging.
•	06 April 2006	Change in the composition of the product.
•	07 March 2006	To include an alternative quality control site, replacement of the site responsible for batch release and replacement of a manufacturing site.

•	26 September 2005	Addition of a new test for the finished product.
•	24 May 2005	Changes to the finished product specification.
•	29 April 2005	To change the name of a manufacturer of the finished product.
•	06 April 2005	Changes to the manufacturing process, addition of a manufacturer and a change in the name of a manufacturer.
•	07 December 2004	Change in the name of a supplier.