Veterinary Medicines Directorate

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Post Authorisation Assessments

Atopica 100 mg/ml Oral Solution for Cats and Dogs

Vm 00879/3015

•	28 April 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	23 January 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.
•	11 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. Minor changes: – to an approved test procedure for active substance. Minor changes: – to an approved test procedure for active substance. Submission of a new certificate of suitability.
•	28 July 2023	Update Pharmacovigilance sections to align with EU.
•	28 July 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.
•	03 November 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	08 July 2021	Change in the name and address of a manufacturer of the active substance.
•	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.
•	24 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.
•	05 June 2019	Change in the safety database of an existing

		pharmacovigilance system as described in the DDPS.
•	28 August 2018	Change in shape or dimensions of the container or closure (immediate packaging). Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	20 July 2017	Change of measuring/administration device without CE markings which is not an integrated part of the primary packaging.
•	29 June 2017	Increase in the shelf-life of the finished product after first opening, from 60 days to 84 days.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	18 January 2017	Change in the legal entity and distributor from Novartis Animal Health UK Ltd to Elanco Europe Ltd.
•	13 January 2017	Change in the fill volume of the finished product. Change in the invented name of the finished product from Atopica 100 mg/ml Oral Solution for Cats to Atopica 100 mg/ml Oral Solution for Cats and Dogs. Addition of administration device without CE markings which is not an integrated part of the primary packaging. Addition of a non-food producing target species.
•	13 January 2017	Change in name of the manufacturer responsible for batch release.
•	01 August 2016	Renewal - UK as CMS
•	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.
•	19 November 2015	Deletion of an odour test Widening of assay and density limits for ammonium hydroxide Use of an alternative demulsifier Use of an alternative to process water Deletion of a manufacturer Tightening of specifications Addition of an IR identity test Deletion of a test for a specification Replace an in process test Deletion of tests from raw material specifications Minor changes to the fermentation process carried out at the a manufacturing site Minor changes to the purification process at a manufacturing site
•	07 October 2015	Amendments to the finished product storage condition wording.
•	16 October 2014	Change in the name of the manufacturer. Additional site for secondary packaging of the product.
•	30 April 2014	Changes to an existing pharmacovigilance system.
•	06 March 2014	Change in specification of an active substance and change to comply with Ph. Eur. Pharmacopoeia.
•	07 February 2014	Change to the MAH address in Portugal only.

•	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.