

Post Authorisation Assessments

Atopica 50 mg Soft Capsules for Dogs Vm 52127/5092

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| 28 July 2025 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). |
| 16 April 2025 | Change of Marketing Authorisation Holder from Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, D-27472 Cuxhaven, Germany. |
| 10 July 2024 | Minor editorial changes to package leaflet and labelling if inclusion in an upcoming procedure is not possible. |
| 27 June 2024 | Addition of a new specification parameter to the finished product specification with its corresponding test method. Deletion of a non-significant specification parameter of the finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for an excipient. Minor changes to an approved test procedure for an excipient. Minor changes to an approved test procedure for an excipient. |
| 14 December 2023 | 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. |
| December 2023 | Change in the name or address of a manufacturer of the active substance. |
| 23 June 2023 | Pharmacovigilance sections update to align with EU. |
| 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. |
| 14 September 2022 | Tightening of in-process limits of the active substance. Minor changes to a test method of the active substance. Minor changes to a test method of the active substance Addition of a new Ph.Eur from a new manufacturer for a non-sterile active substance. |
| 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. |

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| | 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. |

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| | 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. |
| 11 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. |