



Post Authorisation Assessments

Vetoryl 120 mg Hard Capsules for Dogs Vm 50406/3015

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| 01 April 2026 | Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. |
| 14 January 2026 | Tightening of specification limits of an excipient. Minor changes to an approved test procedure for an excipient. |
| 14 October 2025 | Harmonisation of the quality dossier. |
| 29 May 2025 | Submission of an updated European Pharmacopoeial TSE Certificate of suitability for an excipient. Submission of an updated European Pharmacopoeial TSE Certificate of suitability for an excipient. Submission of a new European Pharmacopoeial TSE Certificate of suitability for an excipient. |
| 15 April 2025 | Substantial changes in the updated version of the ASMF for trilostane from the currently authorised manufacturer. |
| 03 April 2025 | Addition of a new specification parameter to the specification with its corresponding test method. Addition of a new specification parameter to the specification with its corresponding test method. Addition of a new specification parameter to the specification with its corresponding test method. Deletion of a test procedure for the active substance. Deletion of a non-significant specification parameter of an active substance. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. |
| 03 April 2025 | Submission of a new Ph. Eur. certificate of suitability for a starting material used in the manufacturing process of the active substance. |
| 25 February 2025 | Minor changes:- to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device. |
| 05 February 2025 | Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands. |
| 01 December 2024 | Uniformity of dosage units is introduced to replace the currently registered method. |
| 01 December 2024 | Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter in the specification of the finished product. |

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| 01 December 2024 | Uniformity of dosage units is introduced to replace the currently registered method. |
| 01 December 2024 | Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range. Change in the specification parameters and/or limits of the finished product: - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Change in the specification parameters and/or limits of the finished product: - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Change in the specification parameters and/or limits of the finished product: - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product. Harmonisation of the quality dossier. |
| 20 October 2024 | VeDDRA LLT weakness moved from very rare frequency to rare frequency. Alteration of wording describing mortalities following chronic administration dosage levels. |
| 02 July 2024 | Addition of a new specification parameter to the specification with its corresponding test method. Minor changes to an approved test procedure for an in-process test for active substance. Addition of a supplier of packaging components or devices (when mentioned in the dossier). Addition of a supplier of packaging components or devices (when mentioned in the dossier). Addition of a supplier of packaging components or devices (when mentioned in the dossier). Addition of a supplier of packaging components or devices (when mentioned in the dossier). |
| 02 July 2024 | Changes in the manufacturing process of the active substance. |
| 19 March 2024 | Change in the address or contact details of a manufacturer or supplier of the starting material, used in the manufacture of the active substance where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. Change to comply with Ph. Eur. for the starting material used in the manufacture of the active substance. Changes to the quality part of the dossier: Deletion of a test procedure for a reagent used in the manufacture of the active substance. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance. |
| 27 February 2024 | Change in qualitative composition of the immediate packaging for a solid pharmaceutical form for a finished product. |
| 28 November 2023 | One-off alignment of the product information with version 9.0* of the QRD template. |
| 16 November 2023 | Minor changes – to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device. |
| 07 September 2022 | Deletion of a non-significant in-process test during the manufacture of the finished product. |
| 28 July 2022 | Editorial changes to Part II B of the dossier for the 10 mg hard capsules. Editorial changes to Part II C of the dossier for the 5 mg and 60 mg |

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| | hard capsules. Editorial changes to Part II F of the dossier for the 30 mg, 60 mg and 120 mg hard capsules. |
| 29 March 2022 | Deletion of a non-significant in-process test applied during the manufacture of the finished product. |
| 16 November 2021 | Addition of a new specification parameter to the specification with its corresponding test method of the finished product. |
| 23 September 2021 | Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product. |
| 09 February 2021 | Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. |
| 21 April 2020 | Deletion of manufacturing site where batch control takes place. |
| 17 October 2019 | Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability from a new / already approved manufacturer. Deletion of Ph. Eur. TSE certificates of suitability. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. |
| 24 September 2019 | Changes to a test procedure for the finished product. |
| 07 August 2019 | Update to the ASMF. |
| 18 June 2019 | Addition of a manufacturer responsible for batch release including batch control/testing. |
| 02 April 2019 | Minor change to an approved test procedure for the active substance. |
| 12 February 2019 | Changes to an existing pharmacovigilance system as described in the DDPS. |
| 08 February 2019 | Introduction of a new site of manufacture. |
| 01 August 2018 | Change in RMS from UK to IE. |
| 02 February 2017 | Changes to the labelling and package leaflet. |
| 17 May 2016 | Deletion of a TSE certificate. Submission of a new TSE certificate. Submission of an updated TSE certificate. Submission of a new TSE certificate. Submission of a new TSE certificate. |
| 25 November 2015 | Additional site for batch testing of the finished product. |
| 21 May 2015 | Submission of updated Ph. Eur. Certificates of Suitability from an already approved manufacturer |
| 01 May 2015 | Change in name of a manufacturer of the active substance |
| 20 November 2014 | Updates to the labelling and package leaflet. |
| 10 October 2014 | Change of MA holder address. |
| 06 March 2014 | Significant change to the SPC with regard to clinical data. |
| 14 November 2013 | Grouped variation to update the DMF, amend the raw materials specifications, update the manufacturing methods, and to optimise the active substance manufacturing method. |
| 03 May 2012 | Grouped variation to update TSE Certificates of Suitability as well as the addition of a new Certificate of Suitability for an active substance manufacturer. |
| 02 March 2012 | Change in the manufacturer of the active substance. |
| 09 December 2011 | To change the ink used to mark the capsules. |
| 01 April 2011 | Changes to an existing pharmacovigilance system as described in the |

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| | DDPS. |
| 15 December 2010 | Change of Distributor. |
| 06 October 2010 | To change the Marketing Authorisation Holder. |
| 17 September 2010 | Change in immediate packaging of the finished product. |
| 17 September 2010 | Submission of new or updated Ph. Eur Certificates of Suitability. |
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| 17 September 2010 | Submission of new or updated Ph. Eur Certificates of Suitability. |
| 07 June 2010 | Renewal |
| 03 October 2008 | Change active/intermediate batch size. |
| 05 July 2007 | Change test procedure for active/active component . |
| 01 June 2007 | Change shelf life of finished product as packaged for sale. |
| 01 June 2007 | Change finished product test procedure. |
| 01 June 2007 | Change finished product test procedure. |
| 16 May 2007 | Change/addition of imprints/bossing/markings on tabs or capsules. |
| 08 March 2006 | Change of distributor. |