Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Equest Pramox 19.5 mg/g + 121.7 mg/g Oral Gel

Vm 42058/5148

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| • | 19 December 2023 | Updates to Section 4.6 of the SPC and corresponding section in PL: Digestive discomfort (colic, loose stool) has been observed in very rare cases based on post-marketing surveillance data. |
| • | 20 March 2023 | Deletion of a manufacturer of an active substance. |
| • | 15 March 2022 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 23 July 2020 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 10 January 2020 | Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP. |
| • | 17 April 2019 | Changes (Safety/Efficacy) in the Veterinary Medicinal Product |
| • | 01 April 2019 | Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR. |
| • | 07 November 2018 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 10 July 2018 | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. |
| • | 18 April 2018 | Introduction of a re-test period of the active substance. |
| • | 14 February 2018 | Changes to the SPC/product labelling/package leaflet following an Article 35 referral. |
| • | 09 January 2018 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 09 November 2017 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 08 September 2016 | Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics. |
| • | 13 July 2016 | Changes to section 4.6 of the SPC. |
| • | 06 July 2016 | Submission of a new Ph. Eur. certificate of suitability and deletion of a Ph. Eur. certificate of suitability. |
| • | 05 June 2015 | Change in the QPPV and/or QPPV contact details and/or back-up procedure |
| • | 04 February 2015 | Addition of a new test method to the finished product |

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| | | specification. |
| • | 04 July 2014 | Submission of an updated Ph. Eur. Certificate of suitability. |
| • | 30 October 2013 | Change of name for the finished product manufacturer responsible for batch release and change of QPPV contact details. |
| • | 30 October 2013 | Submission of new clinical data to support the modification of the SPC to allow the use of the product in breeding, pregnant or lactating mares. |
| • | 23 October 2013 | Change to the name of the MAH from Pfizer to Zoetis in AT, BE, FR and LU only. |
| • | 31 July 2013 | Change of MAH and distributor to Zoetis UK Limited. |
| • | 18 July 2013 | Change to the immediate packaging design and increase in size resulting in a change of supplier, changes to the finished product specification and increase in batch size of the finished product. |
| • | 27 August 2012 | Submission of a new Ph. Eur. Certificate of Suitability for an active substance. |
| • | 13 June 2012 | Introduction of a new Pharmacovigilance system. |
| • | 04 November 2011 | Change in name and/or address of the manufacturer of the finished product. |
| • | 02 September 2011 | Submission of a new/updated Ph. Eur. Certificate of suitability. |
| • | 11 March 2011 | Change in name/address of MAH. |
| • | 19 November 2010 | Renewal: UK as CMS |
| • | 13 October 2010 | To change the MAH and distributor from ‘Fort Dodge Animal Health Ltd’ to ‘Pfizer Limited’. |
| • | 09 February 2009 | To comply with Ph. Eur to change the specifications of the active substance. |
| • | 22 September 2008 | To add a new manufacturer for the active ingredient. |
| • | 22 February 2008 | To change the range of the specification of filled syringe weight. |
| • | 22 February 2008 | To change the primary packaging. |
| • | 30 May 2007 | To increase the shelf life from 18 to 24 months |
| • | 27 February 2007 | To change the packaging material not in contact with finished product formulation. |
| • | 29 August 2006 | To increase the shelf life of the finished product. |