Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Heptavac P Plus
Vm 01708/3029

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| • | 18 May 2024 | To align the product information with version 9.0 of the QRD templates. |
| • | 10 November 2023 | Change to comply with Ph. Eur. |
| • | 30 August 2023 | To update of the sterility test procedure according Ph.Eur. 2.6.1 performed on the finished product; minor adjustments have been made to the method suitability test to improve recovery of the A. brasiliensis reference strain. |
| • | 30 June 2023 | To update of the sterility test procedure performed on the finished product according to Ph.Eur. 2.6.1. Minor adjustments to the method suitability test to improve recovery of the A. brasiliensis reference strain. |
| • | 17 April 2023 | Addition of an in vitro potency ELISA for C. perfringens type C beta toxoid.<br>Optimisation of the statistical analysis method for the Fab ELISA to confirm M. haemolytica identity and P. trehalosi identity/potency.<br>Addition of Intervet International B.V., Boxmeer, NL, as finished product Quality Control test site for the C. perfringens type C beta toxoid potency test, M. haemolytica identity test and P. trehalosi identity/potency test. |
| • | 05 April 2023 | Addition of an in vitro toxicity test for C. chauvoei cells and toxoid.<br>Addition of the use of bovine liver extract in Clostridia growth medium. |
| • | 20 February 2023 | Addition of an in vitro toxicity test for C. chauvoei cells and toxoid.<br>Addition of the use of bovine liver extract in Clostridia growth medium. |
| • | 24 June 2022 | Change of a test procedure for the active substance.<br>Change of a test procedure for the active substance.<br>Change of a test procedure for the active substance. |
| • | 16 June 2022 | Changes to a test procedure for the finished product. |
| • | 16 February 2022 | Change to a test procedure (including replacement or addition) for the active substance.<br>Change in the manufacturing process of the active substance.<br>Change in the manufacturing process of the active substance.<br>Change in the manufacturing process of the active substance. |

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| | | Change in the manufacturing process of the active substance.<br>Change in the manufacturing process of the active substance.<br>Change in the manufacturing process of the active substance. |
| • | 05 October 2021 | Update of the test procedure to comply with the updated general Ph. Eur monograph.<br>Minor changes to an approved test procedure of the finished product.<br>Minor changes to an approved test procedure of the finished product.<br>Changes to a test procedure for the finished product.<br>Changes to a test procedure for the finished product.<br>Changes to a test procedure for the finished product.<br>Changes to a test procedure for the finished product.<br>Changes to a test procedure for the finished product.<br>Addition of a site where batch control/testing takes place. |
| • | 07 September 2021 | Summary of Product Characteristics and product literature updated with regard to pharmacovigilance data. |
| • | 15 June 2021 | Change in the manufacturing process of the finished product. |
| • | 11 January 2021 | Changes to the labelling and/or package leaflet. |
| • | 01 October 2020 | Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| • | 11 September 2020 | Change in the name of a manufacturer used in the manufacture of the active substance. |
| • | 14 August 2020 | Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited. |
| • | 26 April 2019 | Addition of a manufacturer responsible for batch release of the finished product. |
| • | 18 May 2018 | Change in the manufacturing process of the active substance.<br>Change in the manufacturing process of the active substance. |
| • | 01 May 2018 | Change in RMS from UK to IT. |
| • | 01 November 2016 | Change in name of manufacturer of the active substance. |
| • | 02 December 2015 | Change in the specification parameters and/or limits of the finished product |
| • | 08 November 2012 | Change to manufacturing process of an active substance<br>Change to in-process test for an active substance |
| • | 30 March 2012 | Change of name of manufacturer of the finished product |
| • | 14 July 2010 | Update of detailed description of manufacturing process |
| • | 01 September 2009 | Change of address of MAH in Portugal only |
| • | 02 April 2008 | Renewal |
| • | 13 October 2006 | Change to manufacturing process of the active substance |
| • | 20 May 2005 | Change of distributor |
| • | 17 January 2005 | Change to test procedure performed on a starting material used in the manufacture of the active substance |
| • | 12 July 2004 | Repeat use |

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| • | 19 March 2004 | Updates to the SPC |
| • | 07 May 2003 | Renewal |
| • | 13 November 2002 | Change to specification of the finished product |
| • | 10 September 2002 | Addition of 2 manufacturing sites for labelling and packaging<br>Change to shape of packaging |
| • | 31 January 2002 | Change of supplier of a reagent used in the production of the finished product |
| • | 07 November 2001 | Change to the manufacturing process of the active substance |
| • | 31 August 2001 | Addition of a distributor |
| • | 11 May 2001 | Change of product name from 'Heptavac P New' to 'Heptavac P Plus' |
| • | 09 February 2001 | QC Procedures |
| • | 08 February 2001 | Change to manufacturer of the active substance |
| • | 01 August 2000 | Change to specification of the active substance |
| • | 31 March 2000 | Change of name and address of the MAH |
| • | 29 March 2000 | Change to specification of the active substance |
| • | 29 October 1999 | Change of shelf life from 12 months to 24 months<br>Change to manufacturing process of the active substance<br>Change of product formulation<br>Change to QC procedures |
| • | 31 December 1998 | Minor change in manufacturing procedure of the active substance |