Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Cestem Flavoured Tablets for Medium and Small Dogs

Vm 15052/4040

| | | |
|---|---|---|
| • | 15 December 2023 | Deletion of an obsolete parameter in the specification parameters of the finished product. (NI) |
| • | 14 December 2023 | Minor changes to an approved test procedure for an excipient. (NI) |
| • | 24 July 2023 | Change in test procedure for the finished product. |
| • | 10 May 2023 | Minor changes to an approved test procedure for an excipient. |
| • | 18 April 2023 | Change in test procedure for the finished product. |
| • | 29 March 2023 | Deletion of a non-significant specification parameter of the finished product. |
| • | 04 October 2022 | Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom. |
| • | 24 March 2022 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>Introduction of a re-test period of the active substance.<br>Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. |
| • | 02 March 2022 | Addition of a site where batch control/testing takes place. |
| • | 20 May 2021 | Changes to the labelling and/or package leaflet. |
| • | 22 December 2020 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 20 August 2020 | Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning a PSUR. |
| • | 09 December 2019 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 06 February 2019 | Change to comply with an update for the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.<br>Submission of an updated Ph. Eur. certificate of suitability |

| | | |
|---|---|---|
| | | for an active substance from and already approved manufacturer.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from and already approved manufacturer.<br>Addition of a new Ph. Eur certificate of suitability for an active substance from a new manufacturer. |
| • | 13 June 2018 | Change in RMS from UK to NL. |
| • | 23 November 2017 | Addition of a secondary packaging site of the finished product.<br>Addition of a primary packaging site of the finished product. |
| • | 19 September 2017 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 19 September 2017 | Change in the name and/or address of the MAH in Spain only. |
| • | 10 March 2017 | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. |
| • | 19 April 2016 | Submission of an updated certificate of suitability. |
| • | 22 December 2015 | Updating of the DDPS system. |
| • | 09 July 2015 | Renewal – UK as RMS. |
| • | 06 February 2015 | Change to the MAH address in Slovakia and Czech Republic only. |
| • | 21 August 2014 | Minor change in the manufacturing process of the finished product. |
| • | 09 January 2014 | Change in the batch size of the active substance, and change to manufacturing process of the active substance. |
| • | 09 January 2014 | Submission of a new or updated European Pharmacopoeia certificate of suitability. |
| • | 31 December 2013 | Submission of a new or updated European Pharmacopoeia certificate of suitability. |
| • | 11 October 2013 | Changes to an existing pharmacovigilance system as described in the DDPS. |
| • | 18 July 2013 | Changes to an existing pharmacovigilance system as described in the DDPS. |
| • | 02 March 2012 | Submission of a new or updated European Pharmacopoeia certificate of suitability. |
| • | 02 March 2012 | Submission of a new or updated European Pharmacopoeia certificate of suitability. |
| • | 05 January 2012 | To change the name and address of the MAH in Italy only. |
| • | 25 October 2011 | To change the address of the MA Holder. |
| • | 15 September 2009 | MRP procedure – UK as RMS. |
| • | 17 August 2009 | Submission of a new or updated European Pharmacopoeia certificate of suitability. |
| • | 28 July 2009 | New primary and secondary packaging site |
| • | 13 July 2009 | Packaging site for product added. |