



Post Authorisation Assessments

Drontal Dog Tasty Bone 150/144/50 mg Tablets

Vm 08007/4164

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| • | 14 December 2023 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI) |
| • | 14 July 2023 | Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance, for a starting material |
| • | 14 July 2023 | Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. |
| • | 22 April 2022 | Updates to package leaflet regarding dosage instructions. |
| • | 08 October 2021 | Introduction of a new pharmacovigilance system. |
| • | 05 November 2020 | Change of MAH from Bayer Animal Health GmbH, 51368 Leverkusen, Germany to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS. |
| • | 26 June 2020 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer |
| • | 09 June 2020 | Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Bayer Animal Health GmbH, 51368 Leverkusen, Germany. |
| • | 15 October 2019 | Renewal – UK as CMS |
| • | 26 October 2018 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS |
| • | 01 August 2018 | Submission of a new Ph. Eur. certificate of suitability for an active substance used in manufacturing process from a new manufacturer. |
| • | 10 January 2018 | Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD. |
| • | 20 July 2016 | Submission of an updated certificate of suitability. Increase in the shelf life of the finished product from 2 years to 3 years. |
| • | 30 June 2016 | Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of |

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| | | the same MAH. |
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