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Post Authorisation Assessments

Johnsons Fipronil 50 mg Spot-On Solution for Cats Vm 02000/4329

| 22 December 2023 Introduction of a summary of the PSMF not already covered elsewhere in this Annex. (NI) 14 December 2023 Change in dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (NI) Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI) Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI) Change in dimensions of the container or closure of a non-sterile finished product. 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. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. O6 January 2021 Minor changes to an approved test procedure of the finished product. O6 January 2021 Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. One are in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. One are in the QPPV of an existing pharmacovigilance system as described in the DDPS. Addition of a manufacturer responsible for batch release of the finished product. QB June 2017 Addition of a secondary packaging site of the finished product. One 21 December 2016 Change in the invented name of the veterinary medicinal product from Fleanil to Bolfo in Germany only. | | 00 D : 0000 | 1 (1 () () () () () |
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| 29 August 2014 Changes to the DDPS. | • | 21 December 2016 | Change in the invented name of the veterinary medicinal |
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| • | 16 July 2014 | Addition of a manufacturer responsible for batch release. |
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| • | 26 June 2014 | Addition of a site for secondary assembly. |
| • | 24 June 2014 | Change to the invented name of the product from 'Spot |
| | | and Clear 50 mg Spot-on Solution for Cats' to 'Johnsons |
| | | Fipronil 50 mg Spot-On Solution for Cats'. |
| • | 03 June 2014 | Change of distributor. |
| • | 23 October 2013 | Extension of shelf life of the product as packaged for sale |
| | | from 2 years to 3 years. |
| • | 02 August 2013 | Change in the name of the medicinal product in Germany |
| | | only from Pestigon 50 mg Spot-On Solution for Cats to |
| | | Fleanil 50 mg Spot-On Solution for Cats. |
| • | 12 April 2013 | Addition of a new therapeutic indication. |
| • | 21 February 2013 | To change the legal category from NFA-VPS to AVM- |
| | | GSL. |
| • | 16 November 2012 | To update the text on the outer and immediate |
| | | packaging. |
| • | 29 June 2012 | Removal of an indication. |