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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Suprelorin 4.7 mg Implant for Dogs and Cats

Vm 05653/5017

•	13 April 2024	Update of package leaflet.
•	12 September 2023	Addition of an alternative dosing device/actuator with an optimised design.
•	07 June 2023	Deletion of - a non-significant specification parameter in the specification parameters or limits of the immediate packaging of the active substance or the finished product. Deletion of a non-significant specification parameter of an active substance.
•	21 March 2023	Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes.
•	19 January 2023	Updates to SPC Section 4.6 and Leaflet Section 6 to implement the outcome of a procedure concerning risk management measures in pharmacovigilance related to veterinary medicinal products.
•	28 December 2022	Deletion of a non-significant test in the specification parameters of the finished product.
•	28 December 2022	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier.
•	01 November 2022	Change in address of microbiological testing site for the finished product.
•	03 August 2022	Addition of indication for prepubertal female dogs: 'For the induction of temporary infertility to delay the first oestrus and heat signs, and to prevent pregnancy at a young age in intact and healthy sexually immature female dogs. The implant should be administered between 12 and 16 weeks of age.' Addition of cats (male) as a new target species and associated indication: 'For the induction of temporary infertility and suppression of urine odour and of sexual behaviours such as libido, vocalisation, urine marking, and aggressiveness in intact male cats from 3 months of age.'
•	11 May 2022	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	19 January 2022	Minor change in the manufacturing process of the finished product.
•	18 February 2021	Grouped variation for the deletion of a test procedure for the immediate packaging of the finished product, tightening of specification limits used in the manufacturing process of the active substance, update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product, tightening of specification limits of the finished product and change in the batch size (including batch size ranges) of the finished product.