Veterinary Medicines Directorate
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Post Authorisation Assessments

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

Stelfonta 1 mg/ml Solution for Injection for Dogs

Vm 52489/5000

•	15 March 2024	Changes to the quality part of the dossier to comply with an update of the relevant monograph of the Ph. Eur. Changes to the quality part of the dossier to comply with an update of the relevant monograph of the Ph. Eur. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	08 December 2023	Minor changes in the manufacturing process of the active substance. Minor changes in the manufacturing process of the active substance. Introduction or increase in an overage for the active substance.
•	30 August 2023	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority- Including recommended wording as requested following review of a PSUR. One-off alignment of the product information with version 9.0* of the QRD template.
•	14 August 2023	Minor change to an approved test procedure for the active substance. Minor change to an approved test procedure for the active substance. Minor changes to an approved test procedure for a starting material used in the manufacture of the active substance. Minor changes to an approved test procedure for an intermediate used in the manufacture of the active substance. Minor changes to an approved test procedure for a starting material used in the manufacture of the active substance. Minor changes to an approved test procedure, for a starting material, reagent or intermediate used in the manufacturing process of the active substance
•	20 December 2022	Addition of a new specification parameter to the specification with its corresponding test method for the active substance.
•	01 November 2022	Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test. Deletion of a residual solvent test.
•	20 December 2021	Changes to a test procedure for the active substance.

•	28 July 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture Change in the specification parameters and/or limits of an active substance Change in the specification parameters and/or limits of an active substance Addition of a new specification parameter with its corresponding test method used in the manufacturing process of the active substance Addition of a new specification parameter with its corresponding test method used in the manufacturing process of the active substance Addition of a new specification parameter with its corresponding test method used in the manufacturing process of the active substance Addition of a new specification parameter with its corresponding test method used in the manufacturing process of the active substance
•	08 July 2021	Changes to the quality control testing arrangements for the active substance. Deletion of a non-significant specification parameter of the finished product.