



Post Authorisation Assessments

Selames 120 mg Spot-on Solution for Dogs 10.1–20.0 kg

Vm 01656/4147

14 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
06 January 2026	One-off alignment of the product information with version 9.1 of the QRD template.
15 July 2025	Change in the address of a manufacturer of the finished product. (NI).
03 July 2025	Change in the address of a manufacturer of the finished product. (GB)
24 March 2025	Change in the manufacturer of a starting material used in the manufacturing process of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier:- Other changes.
09 January 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI)
10 January 2025	Deletion of a manufacturing site of the active substance. (GB)
10 January 2025	Deletion of a manufacturing site of the active substance. (NI)
18 March 2024	Changes to comply with the Ph. Eur. monograph of the active substance, removal of references to internal test methods and test method numbers. (NI) Change in the address of the manufacturer of the starting material of an active substance. (NI)
04 March 2024	Minor changes to an approved test procedure for the finished product. (NI)
19 April 2023	Unlimited renewal
14 March 2023	Minor changes to an approved test procedure for an in-process test for the finished product - Seal integrity of the bags.
17 January 2023	Changes to comply with the Ph. Eur. monograph of the active substance - Removal of references to internal test methods and test method numbers. Change in the address of the manufacturer of the starting material.
01 September 2022	Extension of the re-test period of the active substance.
22 March 2022	Minor changes to an approved test procedure of the finished product. Minor change of an analytical procedure for an in-process control applied during the manufacture of the finished product.
07 May 2021	Increase in the shelf-life of the finished product as packaged for sale from 2 years to 3 years.
08 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.

