



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Advocate 400 mg + 100 mg Spot-on Solution for Extra-Large Dogs (> 25– 40 kg)

Vm 04895/5000

23 July 2025	Addition of body weight ranges in the product name. Addition of body weight ranges in the product name in outer packaging and package leaflet. Addition of unit dose on pipette and blister. Grey shading of Exp and Lot on blister. Minor editorial changes to the SPC/QRD texts. Addition of pictogram for the ferret target species in the package leaflet. Use of English or Latin INN on blister due to space limitation on multi-lingual blisters. Addition of pictogram for the ferret target species in the outer packaging. Addition of target species weight to the product name.
17 July 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
26 January 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
27 November 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.
11 May 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
18 August 2023	Change in the address of the MAH from Bayer Animal Health GmbH, 51368 Leverkusen, Germany to Elanco Animal Health GmbH, Alfred-Nobel- Str 50, 40789 Monheim, Germany.
21 February 2023	Change in the re-test period of an active substance.
23 June 2022	Addition of a new therapeutic indication.
14 January 2022	Changes in the SPC and product literature intended to implement the outcome of a procedure concerning a PSUR.
24 March 2021	Change in the address of a manufacture of the active substance.