Post Authorisation Assessments

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

Credelio 450 mg Chewable Tablets for Dogs (>11–22 kg)
Vm 52127/5007

09 June 2025	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
07 May 2025	Minor changes to an approved test procedure for the finished product.
13 March 2025	Change in the specification parameters of reagent used in the manufacture of an intermediate. Change in the specification parameters of reagent used in the manufacture of an intermediate. Change in the specification parameters of reagent used in the manufacture of an intermediate. Minor change to the manufacturing process of an active substance intermediate.
13 March 2025	Change in the manufacturer of an intermediate.
27 February 2025	Change in the name or address or contact details of a manufacturer or supplier of a starting material. Deletion of a supplier of a starting material.
06 January 2025	Addition of additional adverse events to Credelio Chewable Tablets for Dogs: Pruritus, Haemorrhagic diarrhoea, Urinary incontinence, Inappropriate urination, Polyuria/ pollakiuria and Polydipsia (and editorial changes to maintain alignment).
13 March 2024	Introduction of a new 18 tablet pack size presentation.
13 March 2024	Change in shape and dimensions of the immediate packaging of a non-sterile finished product.
29 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
11 October 2022	Change in batch size of the active substance.
30 September 2022	New indication: for the treatment of demodicosis.
14 July 2022	Renewal.
01 December 2021	Changes in the manufacturing process of the active substance.
16 April 2021	Change in control of excipient of finished product – variation to extend shelf-life of the excipient meat dry flavour.