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Post Authorisation Assessments

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

Credelio Plus 112.5 mg/4.22 mg Chewable Tablets for Dogs (>2.8 kg - 5.5 kg)

Vm 52127/5034

07 May 2025	Minor changes to an approved test procedure for the finished product.
04 April 2025	Change in the manufacturer of an intermediate used in the manufacturing process of the active substance.
04 April 2025	Addition of a new specification parameter to the specification with its corresponding test method. Change in the specification parameters or limits of reagent used in the manufacturing process of the active substance. Change in the specification parameters of reagents used in the manufacturing process of the active substance. Minor changes:— in the manufacturing process of an active substance.
21 January 2025	Change in the name or address or contact details of: a manufacturer of starting material. Changes to the quality part of the dossier: Deletion of a supplier of a starting material for an active substance.
30 July 2024	One-off alignment of the product information with version 9.0* of the QRD template.
23 February 2023	Addition of a new indication: For the treatment of demodicosis.
31 May 2022	Change(s) in the manufacturing process of the active substance.
19 November 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
21 October 2021	Extension of the shelf-life of an excipient.
28 June 2021	Addition of a manufacturer of a starting material. Changes in the specification parameters of a starting material. Change in the manufacturer of a starting material used in the manufacturing process of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Addition of a manufacturer of a starting material. Changes in the specification parameters of a starting material. Change in the manufacturer of a starting material. Changes in the specification parameters of a starting material. Changes in the specification parameters of a starting material. Change in the manufacturer of a starting material. Addition of a manufacturer of a starting material. Changes in the specification parameters of a starting material. Change in the manufacturer of a starting material. Change in the manufacturer of a starting material. Change in the manufacturer of a manufacturer of a starting material used in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.

Minor change in the manufacturing process of the active substance.
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Deletion of manufacturing site for an active substance manufacturer responsible for the supply of a starting material.