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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 450 mg/16.88 mg Chewable Tablets for Dogs (>11 kg- 22 kg)

Vm 52127/5036

	22 February 2022	Addition of a new indication. For the treatment of demandicable
•	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.
		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.
		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.
		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 name of a manufacturer of a starting material
		used in the manufacturing process of the active substance.
		Change in the address of a manufacturer of a starting material
		used in the manufacturing process of the active substance.
		Minor change in the manufacturing process of the active
		substance.
		Minor change in the manufacturing process of the active
		substance.
		Deletion of manufacturing site for an active substance
		manufacturer responsible for the supply of a starting material.
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