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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.

Exzolt 10 mg/ml Solution for Use in Drinking Water for Chickens

Vm 01708/5036

•	04 May 2024	Change of a measuring or administration device.
•	September 2023	Extension of the shelf life of the finished product after first
		opening.
•	27 April 2023	One-off alignment of the product information with version 9.0* of the QRD template.
		Change in immediate packaging of the finished product - Addition of a new 4 ml bottle.
		Change in pack size of the finished product - Addition of a new 4 ml presentation size.
•	15 March 2023	Editorial changes to part 2 of the dossier.
•	08 March 2023	Addition of an administration device which is not an integrated part of the primary packaging.
•	15 November 2022	Addition of an alternative 1 L HDPE bottle immediate packaging for the finished product.
•	21 June 2022	Change in name of manufacturer of the active substance.
•	01 June 2022	Change in shape and dimensions of the container (immediate packaging) of the finished product.
•	06 May 2022	Approval of Mock-ups.
•	07 March 2022	Renewal.
•	09 February 2022	Changes to the labelling and package leaflet.
•	04 February 2021	Change in the SPC, labelling or package leaflet due to new data.