



Post Authorisation Assessments

AVINEW NEO Effervescent Tablet for Chickens and Turkeys Vm 08327/4266

•	12 April 2023	Changes in the name or address or contact details of a qualified person for pharmacovigilance.
•	19 December 2022	The addition of a new site IDMYK for mycoplasma testing by PCR.
•	23 November 2022	To add an alternative release test for mycoplasma detection by PCR to the existing culture technique.
•	01 November 2022	To register IDMYK site for the 4 concerned products, for the realisation of mycoplasma testing by PCR. The new test by PCR will be performed either on Boehringer Ingelheim LPA site or by IDMYK laboratory, usual subcontractor of LPA for PCR techniques.
•	14 October 2022	To add an alternative release test for mycoplasma detection by PCR to the existing culture technique.
•	18 May 2022	Change in the SPC, labelling or package leaflet due to new data.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 August 2020	Change in the name of the manufacturer of the finished product.
•	September 2020	Addition of turkeys as a target species.
•	22 July 2020	Change in the name of a manufacturer of the active substance.
•	18 June 2020	Change in the name of the manufacturer of the finished product.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	20 September 2019	Renewal - UK as CMS
•	14 August 2019	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	23 November 2017	Change in the manufacturing process of the finished product, including an intermediate used in the

		manufacture of the finished product
•	15 August 2017	Widening of the specification limits of a starting material used in the manufacturing process of the active substance.
•	14 October 2016	Increase in shelf life from 16 to 24 months. Decrease in specification parameters for the finished product.
•	14 January 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure