



Post Authorisation Assessments

Gallivac IB88 NEO Effervescent Tablet for Suspension for Nebulisation for Chickens Vm 08327/4265

•	23 November 2023	Editorial change to part 2E of the dossier.
•	13 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	23 November 2022	To add an alternative release test for mycoplasma detection by PCR to the existing culture technique.
•	29 December 2020	Change in the manufacturing process of the finished product.
•	26 November 2020	Change in the name of the manufacturer of the finished product.
•	24 September 2020	Renewal – National
•	28 August 2020	Change in the name of the manufacturer of the finished product.
•	05 August 2020	Increase in the shelf-life of the finished product, from 15 months to 24 months.
•	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.
•	14 August 2019	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
•	29 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	04 July 2018	Modification of an approved indication.
•	15 August 2017	Widening of the specification limits of a starting material used in the manufacturing process of the active substance.
•	10 May 2017	Changes in the manufacturing process of the finished product. Change in the specification limits of the finished product. Change in the composition (excipients) of the finished product.

•	23 March 2016	Variation to harmonise the SPC and product literature with Ireland.
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