



Veterinary  
Medicines  
Directorate

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## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021,  
please refer to the [EMA](#) website.

### Naxcel 200 mg/ml Suspension for Injection for Cattle Vm 42058/5041

12 May 2025	Change in batch size (including batch size ranges) of active substance. Change in batch size (including batch size ranges) of an intermediate used in the manufacturing process of the active substance. Change in batch size (including batch size ranges) of an intermediate used in the manufacturing process of the active substance.
20 July 2024	Minor change in the manufacturing process of the finished product. Change in holding time of bulk product.
14 May 2024	Deletion of Zoetis Belgium S.A as local representative.
28 April 2024	Change in batch size of active substance or intermediate used in the manufacturing process of the active substance.
08 December 2023	One-off alignment of the product information with the latest version of the QRD templates.
09 August 2023	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance. Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance. Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance and editorial change.
20 February 2023	The variation is to update the dossier with currently used test procedure for the finished product.
31 May 2022	Approval of mock-ups.
10 November 2021	Change in the address of an intermediate supplier. Deletion of supplier of active substance intermediate. Change in the manufacturer of an intermediate used in the manufacturing process of the active substance.
13 July 2021	Deletion of manufacturing site for an intermediate.