



Post Authorisation Assessments

Paramove 49.5% w/w Hydrogen Peroxide Concentrate for Solution for Fish Treatment Vm 31011/5000

•	21 February 2024	Change in any part of the primary packaging material not in contact with the finished product formulation. Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product Deletion of a manufacturing site
•	15 August 2023	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	01 August 2023	Change in any part of the primary packaging material not in contact with the finished product formulation. Change in shape of the container of a non-sterile finished.
•	21 January 2022	Removal of passivation procedure for storage containers with a 5-year life span that are used for storing the active substance.
•	02 July 2021	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	16 June 2021	Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product.
•	10 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 March 2019	Change in RMS from UK to NO.
•	27 September 2018	Change in shape and dimensions of the container and closure.
•	08 November 2017	Renewal – UK as RMS.
•	03 August 2017	Changes to the quality and safety warnings on the SPC and QRD.
•	25 May 2017	Change of legal category from POM-VPS to POM-V.
•	16 November 2016	Addition of an active substance manufacturer. Addition of a manufacturer responsible for batch release and batch testing. Addition of a primary packaging site of the finished product. Increase in batch size of the active substance. Addition of a manufacturing site of the finished product.
•	06 August 2015	Addition of a 26,000 kg pack size of the finished product.
•	29 July 2015	Changes in any part of the (primary) packaging material

		not in contact with the finished product formulation. Change in batch size of the active substance. Change in batch size of the finished product. Deletion of a non-significant specification parameter.
•	27 March 2014	Addition of a manufacturing site of the active substance, change in batch size of the active substance, addition of a manufacturing site of the finished product.