



Post Authorisation Assessments

Salmosan Vet, 500 mg/g Powder for Suspension for Fish Treatment Vm 43684/4002

17 March 2025	Replacement of a manufacturing site for the finished product (GB & NI)
19 January 2025	Minor changes to an approved test procedure for the finished product. (NI)
05 November 2024	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
05 November 2024	Reduction in the shelf-life of the finished product from 3 years to 2 years.
04 May 2024	Changes to the manufacturing process of the active substance.
27 October 2023	Addition of a site of batch release.
02 October 2023	Change in the specification limits of the finished product.
22 December 2022	Change of MAH address from Benchmark Animal Health Limited, Benchmark House, 8 Smithy Wood Drive, Chapletown, Sheffield, S35 1QN to Benchmark Animal Health Limited, Highdown House, Yeoman Way, Worthing' West Sussex, BN99 3HH United Kingdom.
10 November 2022	Change(s) in the SPC, Labelling or Package Leaflet to 4.5 and 4.6.
18 May 2022	Change in the name/address of a manufacturer used in the manufacture of the active substance.
19 January 2022	Deletion of a non-significant specification parameter of an excipient.
25 November 2021	Deletion of a test procedure for the finished product. Deletion of manufacturing site for an active substance.
09 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
29 December 2020	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the finished product. Addition of a manufacturer responsible for importation of the finished product.
08 October 2020	Change of MAH, from FVG (Fish Vet Group) Limited, 22 Carsegate Road, Inverness, IV3 8EX, UK to Benchmark Animal Health Limited, Benchmark House, 8 Smithy Wood Drive, Chapletown, Sheffield, S35 1QN.
28 August 2020	Renewal – UK as CMS.
04 February 2020	Changes to the SPC and QRD text.
14 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
07 November 2018	Change in RMS from UK to NO.

25 July 2018	Change in half-life of the active substance.
20 June 2017	<p>Minor changes to an approved test procedure of the finished product</p> <p>Minor changes to an approved test procedure of the finished product</p> <p>Minor changes to an approved test procedure of the finished product</p> <p>Extension of a re-test period of the active substance.</p> <p>Extension of a re-test period of the active substance.</p> <p>Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months.</p>
25 August 2016	Addition of a manufacturer of the active substance.