

Post Authorisation Assessments

•	30 July 2020	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Change in the SPC, labelling or package leaflet due to
		new data.
•	13 June 2019	Renewal
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	06 December 2018	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of the manufacturer of the finished product.
•	06 December 2018	Deletion of Ph. Eur. TSE certificates of suitability. Submission of an updated Ph. Eur. TSE certificate of suitability from an already approved manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability from an already approved manufacturer.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
•	14 October 2015	Change to in-process limits applied during the manufacture of the active substance.
•	30 September 2015	Change to in-process limits applied during the manufacture of the active substance.

Winvil 3 Micro Emulsion for Injection for Atlantic Salmon