Veterinary Medicines Directorate

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Post Authorisation Assessments

Azasure 500 mg/g Powder for Suspension for Fish Treatment

Vm 49145/4000

•	03 August 2023	Changes in the composition (excipients) of the finished product - Removal of an excipient.
•	11 April 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 November 2020	Change in distributor details. From Naqua Ltd, Unit 8, Starborough Farm, Starborough Road, Nr. Edenbridge, Kent, TN8 5RB to Naqua Ltd, East Block, Building 500, Discovery Park, Ramsgate Road, Sandwich, Kent, CT13 9ND.
•	04 November 2020	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the address of a manufacturer of the finished product, also responsible for batch release.
•	11 February 2020	RMS change from UK to NO
•	29 March 2019	Renewal – UK as RMS
•	03 August 2018	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of local representative.
•	24 July 2018	Change in Distributor details. From: Neptune Pharma Ltd, Unit 8, Starborough Farm, Starborough Road, Nr Edenbridge, Kent, TN8 5RB to Naqua Ltd, Unit 8, Starborough Farm, Starborough Road, Nr Edenbridge, Kent, TN8 5RB
•	17 January 2018	Change in legal entity from Neptune Pharma Ltd to Ground Animal Health Ltd. Change in the address of the distributor to Unit 8, Starborough Farm, Starborough Road, Nr Edenbridge, Kent, TN8 5RB.
•	20 December 2017	Change in address of a manufacturer & importer which is responsible for batch release.
•	24 May 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	20 May 2016	Addition of a site where batch control takes place. Addition of secondary packaging site of the finished product. Addition of pack sizes for the finished product.
•	23 February 2016	To increase the shelf life of the finished product from 18 months to 2 years.
•	27 August 2015	Change in the shelf-life of the finished product, from 1 year to 18 months.

•	13 July 2015	Change in site of batch release of the finished product.
•	02 January 2015	Addition of a site for quality control testing of the finished product. Change to the QPPV. Change to the contractual arrangements for fulfilment of pharmacovigilance obligations.
•	12 December 2014	Increase to the shelf-life of the finished product, from 6 months to 1 year.
•	23 September 2014	To change the invented name of the veterinary medicinal product, from 'Trident' to 'Azasure' in the UK, and from 'Trident vet' to 'Azasure vet' in Norway.
•	17 April 2014	Change in the name and/or address of the Marketing Authorisation Holder.