



Post Authorisation Assessments

Aquapharm 9 Ringer's Solution for Infusion

Vm 32742/4023

•	11 August 2022	Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium.
•	27 September 2018	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. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 July 2015	Addition of an alternative site of quality control testing and batch release. Addition of an alternative site of secondary packaging. Addition of an alternative site of manufacture for the finished product. Changes in the manufacturing process of the finished product. Change in the shelf-life of bags manufactured at the alternative site, to 36 months. Change to the immediate packaging used at the alternative manufacturing site. Change in the specification limits of the finished product.
•	26 February 2015	Change in distributor details.
•	04 June 2013	Change in name/address of MAH
•	25 June 2008	Change in legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	27 November 2007	Renewal
•	28 October 2004	Renewal
•	30 November 2000	Change in formulation Change in manufacturing site of dosage form
•	19 October 2000	Change in sterile container type
•	27 September 2000	Changes to manufacturer of the active substance
•	29 February 2000	Changes to manufacturer of the active substance
•	24 February 2000	Addition of a manufacturing site of dosage form Change of manufacturer of the active substance
•	05 October 1999	Change of manufacturing site of dosage form
•	04 August 1998	Renewal
•	06 January 1998	Change of MAH

