



Post Authorisation Assessments

Aquapharm 18 Solution for Infusion

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| • | 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 batch release and quality control testing site. Addition of an alternative secondary packaging site. Changes in the manufacturing process. Addition of an alternative manufacturing site. Change to the immediate packaging 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 |
| • | 26 January 2001 | Change of ingredient specification |
| • | 30 November 2000 | Change of manufacturing site of the dosage form |
| • | 20 October 2000 | Change in sterile container type |
| • | 24 February 2000 | Addition of a manufacturing site of dosage forms Change in 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 |