



## Post Authorisation Assessments

### Aqupharm 18 Solution for Infusion

Vm 32742/4021

|   |                   |  |
|---|-------------------|--|
| • | 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.<br>Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>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.<br>Addition of an alternative secondary packaging site.<br>Changes in the manufacturing process.<br>Addition of an alternative manufacturing site.<br>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<br>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<br>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  |