



Post Authorisation Assessments

Streptacare Suspension for Injection

•	04 April 2022	Changes in the SPC, Labelling or Package intended to implement the outcome of a PSUR.
•	02 March 2022	Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	30 July 2019	Change in 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.
•	10 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 July 2018	Minor change in the manufacturing process of the finished product. Submission of a new Ph. Eur. certificate of suitability. Submission of an updated Ph. Eur. certificate of suitability. Minor change in the manufacturing process of the finished product.
•	26 February 2018	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	11 May 2017	Addition of a manufacturer of the active substance Addition of a manufacturer of the active substance
•	10 September 2014	To introduce plastic vials as immediate packaging of the finished product. To reduce the shelf-life of the finished product in glass vials, from 2 years to 9 months. Change to the shelf-life specification limits of the finished product.
•	24 July 2013	Change to the distributor address.
•	30 June 2010	Variation to delete an active substance manufacturer.
•	29 October 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	02 November 2007	Renewal.

•	06 March 2007	Transfer of the legal category from POM to POM-V.
•	23 November 2005	Addition of a site of secondary assembly.
•	11 November 2004	Horse Passport Variation.
•	10 May 2004	Variation to make amendments to the product literature.
•	06 February 2004	Renewal.
•	22 December 2003	Addition of an active substance manufacturer.
•	29 May 2003	Change of active substance manufacturer.
•	17 January 2003	Change of meat withdrawal period.