



Post Authorisation Assessments

Trimacare 24% Solution for Injection

•	30 December 2021	Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	22 November 2019	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Increase in batch size of the finished product.
•	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.
•	03 August 2016	Submission of a new certificate of suitability.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	24 July 2013	Change of distributor details.
•	16 July 2013	Grouped variation to update European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers.
•	24 July 2013	Variation to update the distributor.
•	20 January 2009	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	05 November 2008	Variation to update the product literature and outer packaging.
•	14 October 2008	Variation to bring the SPC/ Labelling in line with the Veterinary Regulations, 2005.
•	07 October 2008	Deletion of an active substance manufacturer.
•	15 March 2007	Variation to change the legal category from POM to POM-V.
•	23 February 2007	Renewal.
•	15 November 2005	Addition of a site of assembly.
•	05 November 2004	Change of withdrawal period (horse meat).
•	18 March 2004	Renewal.
•	12 March 2004	Change in a withdrawal period (pig) to bring the product in line with the parent product.

•	12 March 2004	Change in a withdrawal period (cattle) to bring the product in line with the parent product.
•	12 March 2004	Change in a withdrawal period (milk) to bring the product in line with the parent product.
•	12 March 2004	Variation to remove sheep as a target species.
•	06 December 2002	Addition of a secondary manufacturer and assembler.