Veterinary Medicines Directorate

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Post Authorisation Assessments

Amoxycare LA Suspension for Injection 15% w/v

•	11 May 2022	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	01 March 2022	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
•	07 June 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	27 January 2021	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months. Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months.
•	19 November 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	18 September 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved 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.
•	24 January 2019	Increase of withdrawal periods.
•	02 August 2018	Increase in batch size of the finished product. Increase in batch size of the finished product.
•	28 February 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	09 January 2018	Replacement of a supplier of packaging components or devices.
•	03 April 2017	Deletion of a manufacturing site of the active substance. Deletion of a manufacturing site of the active substance. Submission of an updated Ph. Eur. certificate of suitability. Submission of an updated Ph. Eur. certificate of suitability. Deletion of a Ph. Eur. certificates of suitability.
•	18 October 2016	Changes to a test procedure for the finished product.
•	12 July 2016	Update to test procedure for the finished product.
•	20 October 2014	Change to the name of an excipient, from ‘Coconut Oil, Fractioned' to 'Propylene Glycol Dicaprylocaprate'.

•	26 July 2013	Change in distributor details.
•	24 May 2013	Addition of a 500ml pack size, addition of a 250ml pack size and introduction of PET plastic vials in 50ml, 100ml, 250ml and 500ml sizes.
•	18 April 2013	Submission of an updated Ph. Eur. Certificate of Suitability.
•	16 December 2008	Changes to the SPC and labels to bring in line with new legislation.
•	17 July 2008	Addition for a site of part of the manufacturing process of the active substance.
•	30 May 2007	Renewal.
•	19 March 2007	Change in legal category from POM to POM-V.
•	05 August 2005	Addition of a site of assembly.
•	19 September 2003	Change in withdrawal period for cattle, meat/offal from 21 days to 23 days and milk from 60 hours to 84 hours.
•	19 September 2003	Renewal.
•	18 March 2003	Addition of a site of manufacture for the active substance.
•	23 November 1998	Change in withdrawal period for pigs.
•	06 July 1998	Change in withdrawal period for sheep.