



Post Authorisation Assessments

Amoxypen LA 150mg/ml Suspension for Injection

•	11 May 2022	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	15 December 2021	Changes to the SPC and Package leaflet to implement the outcome of a PSUR.
•	15 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	18 May 2021	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months.
•	29 March 2021	Changes to the SPC/product labelling/package leaflet following an Article 35 referral. Changes to the labelling and package leaflet.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	13 November 2018	Increase in batch size of the finished product.
•	03 April 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	06 April 2017	Change in name of the excipient from Coconut Oil, Fractionated to Propylene Glycol Dicaprylocaprate. Update of the test procedure to comply with the updated general Ph. Eur monograph. Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer. Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability.
•	07 November 2016	Change in test procedure for the finished product.
•	25 October 2006	Change in legal category from POM to POM-V Changes to SPC and Product Literature to bring in line with new legislation
•	22 March 2006	Change in site of sterilisation to bring in line with parent product
•	07 February 2006	Addition of a manufacturer of an active substance
•	14 December 2005	Renewal
•	20 April 2005	Change in distributor
•	24 January 2003	Change in withdrawal period for milk from 60 to 79 hours, and meat from cattle from 21 days to 23 days.
•	03 July 2001	Change of distributor

•	14 May 2000	Renewal
•	28 September 2000	Change in withdrawal period for meat from sheep and pigs to 16 days
•	09 June 2000	Update of licence particulars