Veterinary Medicines Directorate

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Post Authorisation Assessments

Unisol 100 mg/ml Solution for Injection for Cattle and Pigs

Vm 32509/4005

•	01 July 2021	Changes to the labelling and/or package leaflet.
•	26 November 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 May 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 May 2017	Repeat Use to add one new Member State.
•	20 January 2017	Submission of a new certificate of suitability.
•	17 May 2016	Renewal – UK as CMS
•	06 April 2016	To add a batch size of 500 litres. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product Addition of a manufacturing site of the finished product Change in the number of units (e.g. tablets*, ampoules*, etc.) in a pack outside the range of the currently approved pack sizes of the finished product
•	10 April 2015	Changes to the SPC and product literature following an Article 35 referral.
•	11 November 2014	Changes to the SPC and product literature following an Article 35 referral.
•	05 October 2012	Removal of indication for E.coli mastitis in cattle and intravenous route of administration.
•	04 January 2012	To add a new manufacturer of the finished product.
•	04 January 2012	Change to batch release arrangements and quality control testing of the finished product.
•	23 November 2011	To change the distributor.
•	01 November 2011	To change the pack size of the finished product.
•	04 August 2011	To change the name of the veterinary medicinal product in Ireland.