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Post Authorisation Assessments

Benzimole 25 mg/ml SC Oral Suspension

Vm 08749/4040

	19 August 2020	Addition of a manufacturer of the active substance or
•	18 August 2020	
	00 1.1. 0040	addition of a site of manufacture.
•	23 July 2019	Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
•	08 August 2017	Change in the specification limits of an excipient
•	02 May 2014	Approval of mock-ups.
•	08 April 2014	Change of distributor.
•	08 April 2014	To change the name from Albensure 2.5% Oral
		Suspension to Benizamole 25 mg/ml SC Oral
		Suspension.
•	27 February 2014	Change to the in-process tests during manufacture of the
	27 1 051441	finished product and changes to the specification
		parameters for the finished product.
•	02 January 2014	Submission of a new Ph. Eur. Certificate of Suitability for
		the active substance manufacturer.
•	03 July 2013	Transfer of MA from Animax Limited to Chanelle
		Pharmaceuticals Manufacturing Ltd.
•	06 April 2011	Change in shape/dimensions of the packaging.
•	19 May 2010	Addition of the statement "do not mix with other products"
		to the SPC and labelling.
•	08 May 2009	Renewal.
•	02 April 2009	Increase of meat withdrawal period for sheep from 4
		days to 5 days.
•	20 November 2008	Variation to bring the SPC and labels in line with the new
		legislation and to transfer the legal category from PML to
		POM-VPS.
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