



Post Authorisation Assessments

Albex 2.5% w/v SC Oral Suspension

Vm 11990/4015

•	19 August 2020	Updated ASMF.
•	16 July 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 July 2019	Replacement to a test procedure for the finished product.
•	25 July 2017	Change in the specification limits of an excipient
•	23 January 2013	Submission of a new certificate of suitability for the active ingredient.
•	06 July 2011	Addition of an active substance manufacturer.
•	16 February 2011	Variation to widen the release and viscosity measurements.
•	08 September 2010	Addition of a warning to the labelling and SPC.
•	13 January 2010	Deletion of a requirement for in-process testing.
•	17 February 2009	Renewal.
•	05 February 2009	Increase in withdrawal period (sheep meat).
•	06 August 2008	Variation to bring the SPC/Labelling in lien with the Veterinary Regulations, 2005.
•	01 May 2008	Change of site address of active substance manufacturer.
•	06 February 2008	Variation to amend the manufacturing process.
•	24 December 2002	Addition of a pack type.
•	21 February 2002	Renewal.
•	06 July 1999	Change of name and address of the Marketing Authorisation Holder.
•	07 July 1998	Change in the product particulars.