Veterinary Medicines Directorate

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Post Authorisation Assessments

Altresyn 4 mg/ml Oral Solution

•	12 May 2022	Increase in batch size (from 10-40 kg to 40-80kg) of the active substance used in the manufacturing process of the active substance. Change in the manufacturing site of the active substance.
•	16 March 2022	Increase in batch size (from 45,5 kg +/- 15% to 45,5 kg +/- 15% or 91,0 kg +/- 15%) of the active substance used in the manufacturing process of the active substance.
•	09 March 2021	Minor changes to an approved test procedure for the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of manufacturing site of the finished product.
•	16 April 2020	Increase in batch size (45.5 kg ± 15 %) of the active substance used in the manufacturing process of the active substance. Change in the manufacturer of a starting material used in the manufacturing process of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	11 April 2019	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products.
•	05 November 2018	Increase in batch size (including batch size ranges) of the active used in the manufacturing process of the active substance.
•	01 August 2018	Repeat Use application to add 3 new member states
•	19 September 2017	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	19 September 2017	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.
•	08 December 2016	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	06 January 2016	Submission of a revised DDPS.
•	13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	05 December 2014	Update of scientific data for an active substance manufacturer.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
•	22 May 2012	Change to withdrawal period from 21 to 9 days.

•	22 February 2012	Repeat Use Comm.
•	13 February 2012	To change the address of the UK Marketing Authorisation Holder.
•	06 January 2012	To change the name and address of the Marketing Authorisation Holder in Italy only,
•	14 December 2011	Renewal – UK as CMS
•	22 April 2010	To add two (540 ml and 1080 ml) presentations permitting the treatment of 6 and 12 animals.