Veterinary Medicines Directorate

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Post Authorisation Assessments

Altresyn 4 mg/ml Oral Solution for Pigs

Vm 15052/5071

January 2025	One-off alignment of the product information with the latest version of the QRD template. Updated indication - authorised for use in sexually mature gilts and weaned primiparous sows to synchonise oestrus
12 January 2025	Addition of a test procedure for the finished product.
22 June 2024	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
18 January 2024	Extension of the retest period of altrenogest. Introduction of a manufacturer of altrenogest supported by an ASMF. (GB)
16 January 2024	Introduction of a new manufacturer of altrenogest supported by an ASMF.
30 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
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.