Veterinary Medicines Directorate

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Post Authorisation Assessments

Fasimec Duo 50 mg/ml + 1 mg/ml Oral Suspension for Sheep

Vm 00879/4072

10 February 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
10 February 2025	Change in the specification parameters or limits of the immediate packaging of the finished product and its corresponding test method.
23 October 2024	Minor change in the manufacturing process of the finished product.
24 October 2024	Change in the batch size of the finished product. Addition of a site of batch control. Minor changes to in-process limits or tests. Deletion of a non-significant in-process test during the manufacture of the finished product.
June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
21 April 2022	Changes to a test procedure for the active substance. Introduction of a new site of manufacture. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance Submission of a new Ph. Eur. certificate of suitability for an active substance (used in manufacturing process of active) / excipient from a new manufacturer.
25 August 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
29 December 2020	Change in the address of the marketing authorisation holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
15 August 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
24 April 2019	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 3 years for 5 litre pack size.
16 April 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
05 July 2018	Change in RMS from UK to IE.
27 June 2017	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance

	used in the manufacturing process of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
21 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
07 March 2017	Introduction of a new pharmacovigilance system.
30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
21 June 2016	Change in the name and address of the Marketing Authorisation Holder from Novartis Animal Health S.p.A to Elanco Italia S.p.A. in Italy only, and from Novartis Sanidad Animal, S.L. to Elanco Spain, S.L.U. in Spain only.
11 May 2016	A change of the active substance manufacturer.
23 December 2015	Submission of an updated certificate of suitability.
28 August 2015	Change of the currently approved in-house testing instruction to fully comply with the newly published current monograph of the Ph.Eur.
27 March 2013	Change to the QPPV contact details and updates to the DDPS that do not affect the pharmacovigilance system.
20 September 2013	Addition of a site for active substance manufacture.
04 July 2013	Change of address of the Marketing Authorisation Holder (MAH).
04 July 2013	Renewal – UK as RMS
17 October 2012	Mutual recognition procedure.
06 September 2012	Change to the DDPS that does not impact on the operation of the pharmacovigilance system.
21 September 2011	To introduce the detailed description of the Pharmacovigilance System.
29 September 2010	To improve the efficacy of the antimicrobial preservation of the formulation.
24 August 2010	To change the name of the manufacturer of the active substance.
24 August 2010	To change the name of the manufacturer of the active substance.
14 July 2010	Variation to add an indication to the use of the product.
25 November 2009	To add a dosing table to the product literature.
25 January 2009	To change the name of the manufacturer of the active substance.
12 August 2008	Decrease in withdrawal period.