Veterinary Medicines Directorate

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Post Authorisation Assessments

CLiKZiN 12.5 mg/ml Pour-On Suspension for Sheep

Vm 00879/3009

18 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
16 May 2023	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products: - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. transitions are not yet agreed upon. One-off alignment of the product information with version 9.0* of the QRD templates.
27 April 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
17 March 2022	Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging). Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
26 April 2021	Deletion of manufacturing site for manufacturer responsible for batch release.
03 February 2021	Replacement of a site where batch control/testing takes place.
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.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
10 May 2019	- Change in the address of a manufacturer supplier of active substance. - Minor change in the manufacturing process of the active substance.

April 2019	Addition of a site where batch testing takes place.
07 February 2018	Change in the RMS from UK to IE.
21 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
10 May 2017	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance. Deletion of a non-significant in-process test applied during the manufacture of the active substance.
07 March 2017	Introduction of a new pharmacovigilance system.
07 February 2017	Tightening of specification limits of an active substance Tightening of specification limits of an active substance Addition of a new specification parameter for an active substance.
02 February 2017	Change in the specification parameters and limits of an excipient. Change in the specification parameters and limits of an excipient.
12 January 2017	Change in the name of a manufacturing site for the finished product.
30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
06 July 2016	Change in the name of an active substance manufacturer.
28 June 2016	Change in the name of the Marketing Authorisation Holder from Novartis Santé Animale to Elanco France in France only.
12 August 2015	Renewal – UK as RMS.
27 March 2014	Change to the QPPV contact details and updates to the DDPS that do not affect the pharmacovigilance system.
16 January 2014	Change to the address of the MAH.
04 July 2013	Change to the address of the MAH.
20 February 2013	Introduction of a new labelling design.
19 August 2011	To change the shelf-life of the veterinary medicinal product as packaged for sale from 24 to 36 months.
15 July 2011	Change in the manufacturer of a starting material used in the manufacturing process of the active substance, change in the specifications of a raw material, change to use a different batch size, and to make minor changes to the manufacturing process.
10 September 2010	To change the contact details of the QPPV.
10 September 2010	To change the QPPV.