Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Deltafort 10 mg/ml Pour-on Solution

Vm 05653/4170

•	04 May 2024	Change in shape or dimensions of the container or closure. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter.
•	04 May 2024	Minor change in immediate packaging of the finished product.
•	17 August 2023	To implement changes in the SPC and package leaflet following the recommendation from the competent authority. Impacted sections of the SPC are sections 4.5, 4.6 and 4.8. Some of the amendments are proposed to ensure that the product literature for Deltafort 10 mg/ml Pour-on Solution is aligned with Deltanil 10 mg/ml Pour-on Solution for Cattle.
•	14 January 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	08 November 2018	Changes to the labelling and package leaflet. Change in distributor details. From Downland Marketing Ltd,Warwick Mill, Warwick Bridge, Carlisle, Cumbria, CA4 8RR to Virbac Ltd, Windmill Avenue, Woolpit Business Park, Woolpit, Bury St Edmunds, Suffolk, IP30 9UP - UK.
•	08 November 2018	Deletion of manufacturing site for an active substance. Change in the invented name of the veterinary medicinal product from Deltacert 10 mg/ml Pour-on Solution to Deltafort 10 mg/ml Pour-on Solution.
•	11 September 2018	National Renewal.
•	09 February 2018	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	05 December 2017	Change in shape or dimensions of the container or closure (immediate packaging)
•	27 July 2017	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 5 years.
•	04 November 2014	Addition of a site responsible for quality control of the finished product. To extend the shelf-life of the veterinary medicinal product as packaged for sale, from 24 months to 36 months. To extend the in-use shelf-life of the product packaged in pouches only, from 12 months to 24 months.
•	25 September 2014	Change to the primary packaging not in contact with the finished product.

		Change to the dimensions of the container or closure of the immediate packaging. Changes in immediate packaging of the finished product.
•	19 September 2014	Minor changes to the approved test procedures for the finished product.