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

## **Post Authorisation Assessments**

## Deltamole 7.5 mg/ml Pour-on Suspension for Cattle Vm 06376/4101

11 April 2025	Minor change in the manufacturing process of the
	finished product.
	Minor change in the manufacturing process of the
22.5	finished product.
09 December 2024	Change in legal entity of MA holder from MSD Animal
	Health UK Limited, Walton Manor, Walton, Milton Keynes
	MK7 7AJ to Intervet International B.V., Wim de
05.1	Körverstraat, 35 5831 AN Boxmeer, The Netherlands.
25 June 2024	Change in the specification limits of an excipient.
31 March 2023	Changes in the SPC, labelling or package leaflet
	intended to implement the outcome of a procedure.
	Changes to the labelling or the package leaflet which are
	not connected with the summary of product
	characteristics.
	Changes to the SPC and / or product literature: -
07.14	Corrections to layout.
07 March 2023	Deletion of a non - significant specification parameter for
04.14   0000	an excipient.
01 March 2023	Deletion of a test procedure for an excipient.
23 February 2023	Deletion of - a non-significant specification parameter in
	the specification parameters or limits of an excipient.
23 February 2023	Deletion of - (a) a test procedure for the active substance
	or a starting material or reagent or intermediate of the
	active substance, or (b) for the immediate packaging of
	the active substance for an excipient or the finished
	product or for the immediate packaging of the finished
2451	product
04 February 2022	Minor changes to an approved test procedure of the
	finished product.
	Minor changes to an approved test procedure of the
	finished product.
	Minor changes to an approved test procedure of the
	finished product.
	Minor changes to an approved test procedure of the
40 Manala 0004	finished product.
18 March 2021	Minor change to an approved test procedure for an excipient.
12 March 2021	Change in the name of the marketing authorisation
	holder from Intervet UK Ltd to MSD Animal Health UK
	Limited.
20 August 2020	Addition of a specification parameter with its
	corresponding test method of the finished product.

15 April 2020	Renewal – National.
13 November 2018	Change in the safety database of an existing
	pharmacovigilance system as described in the DDPS
13 March 2018	Change in the name of a manufacturer used in the
	manufacture of the active substance.
17 January 2017	Changes in the qualitative and quantitative composition
	of the immediate packaging of the finished product.
09 November 2016	Changes to an existing pharmacovigilance system as
	described in the DDPS.
06 September 2016	Change in the name of the supplier of a starting material
	used in the manufacture of the active substance.
	Addition of two manufacturers of an intermediate used in
	the manufacturing process of the active substance.
26 April 2016	Change in the specification limits of the finished product.
01 May 2015	Change in name of the manufacturer of the active
-	substance.
31 March 2015	Change in the specification parameters of an excipient.