Veterinary Medicines Directorate

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Post Authorisation Assessments

Uniferon 20% Solution for Injection

Vm 21674/4000

•	18 September 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance. (QPPV)
•	21 June 2023	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product: - Other changes.
•	25 May 2022	Removal of Distributor details from labelling and package leaflet.
•	15 February 2022	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	15 April 2021	Changes to a test procedure for the finished product. Change in the specification parameters and/or limits of the finished product. Updated version of ASMF.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	25 August 2020	Increase in batch size (from 400-1000L to 400-2000L) of the finished product.
•	07 August 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	29 July 2020	Changes to the labelling and package leaflet.
•	11 December 2019	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.
•	15 May 2018	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.
•	04 November 2015	Minor changes to the ASMF.
•	28 July 2015	Change to distributors.
•	26 March 2015	Change of ATC Vet Code.
•	21 May 2014	Addition of a manufacturing site responsible for manufacture of the finished product including primary and secondary packaging.
•	12 December 2012	Change of ATC Vet Code from QB03AC90 to QB03AC06.

•	07 November 2012	Addition of a pack size.
•	09 February 2011	Removal of a finished product test.
•	28 September 2010	Introduction of new packaging design, introduction of an injector to the packaging, introduction of a new pack size.
•	15 June 2010	Addition of a contract manufacturer for the manufacture of the finished product.
•	27 January 2010	Update of an Active Substance Master File.
•	15 September 2009	Renewal
•	13 August 2007	Harmonisation variation
•	10 January 2007	Changes to the SPC and product literature to bring them into line with new legislation.
•	13 December 2006	Change to specification limits.
•	14 September 2006	Addition of an active substance manufacturing site.
•	03 May 2006	Change of product name from Leodex 20% to Uniferon 20%.
•	21 March 2006	Change to batch release arrangements and quality control testing of the finished product.
•	09 March 2006	Change of MAH name.
•	17 October 2005	Renewal.
•	05 August 2005	Addition of a distributor.
•	25 May 2005	Change to labelling relating to the name of the MAH.
•	18 July 2000	Renewal.