



Post Authorisation Assessments

Uniferon 200 mg/ml Solution for Injection for Pigs (piglet) Vm 21674/4000

30 March 2026	Amendments to the safety information related to Adverse events and Symptoms of overdose, in both SPC and Package leaflet. Change in the administration description from 3-4 to 1-4 days of age. Change to the meat and offal withdrawal period for pigs. One-off alignment of the product information with version 9.0 of the QRD templates.
30 January 2025	Replacement of a test procedure for the finished product.
18 January 2025	Deletion of a manufacturing site for a finished product, responsible for batch release and assembly of dosage form.
01 July 2024	Change in a part of the packaging material not in contact with the finished product formulation.
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.