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Post Authorisation Assessments

Versifel CVR

Vm 60021/3034

20 January 2025	Change in legal entity of MA holder for Northern Ireland from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co. Dublin, Ireland.
14 June 2024	 a. The addition of acceptable countries of origin as source for the porcine pancreas used to make the porcine trypsin powder. b. The removal of the countries of origin for the lactose used in the production process of porcine trypsin. c. To make some editorial changes in the TSE risk assessment.
25 March 2024	Change in the source of a starting material used in the manufacturing process of the active substance.
22 September 2021	Update of the product information in line with the latest QRD template.
14 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
18 January 2019	Addition of a new in-process test and limit applied during the manufacture of the active substance. Change in the specification parameters of the finished product.
23 October 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
09 November 2016	Change in the composition (excipients) of the finished product.
10 June 2015	Update to the DDPS
08 August 2014	Renewal procedure.
29 May 2014	Minor changes to the SPC and product literature.
29 May 2014	Change of MAH from Pfizer Ltd to Zoetis UK Limited. Change of distributor from Pfizer Ltd to Zoetis UK Limited. Change of name of the manufacturer. Change to the pharmacovigilance system.
15 March 2013	To update the SPC and product literature following approval of a compatibility claim for use with Versifel FeLV.
21 November 2012	Changes to finished product tests.
13 June 2012	Changes to existing pharmacovigilance system as described in the DDPS.
15 June 2011	To vary the current Marketing Authorisation, registered via Informed Consent to a full Marketing Authorisation.
30 March 2010	Addition of Suppliers of materials of animal origin sourced from BSE free countries.