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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

Purevax RCPCh FeLV Lyophilisate and Solvent for Suspension for Injection

Vm 04491/5056

•	24 October 2023	Update to the description of starting materials of biological origin.
•	13 October 2023	Minor changes to processes relating to the equipment.
•	14 July 2023	To add an alternative method for the multiplication of CrFK cells in biogenerator.
•	27 April 2023	Change in the storage temperature of the MCB and WCB. Update to the quality control testing of the IRC5 WCB and MCB+20 cell lines used for the manufacturing of the feline panleucopenia active ingredient.
•	26 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	28 March 2023	G.I.18 Product information update.
•	20 December 2022	To add use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
•	03 November 2022	Editorial change of the range for osmolality for stabiliser 49 to 320–356 mOsm/kg.
•	18 August 2022	Deletion of a manufacturer of an active substance.
•	05 August 2022	To increase the maximum release titre of the feline herpesvirus component of Purevax vaccines from 10^6.2 CCID50/dose to 10^6.5 CCID50/dose and to align the titre across the documents to be expressed in units/dose.
•	06 May 2022	Changes to SPC & product literature following a periodic safety update report (PSUR)
•	17 March 2022	Change of a test procedure for the active substance. Changes in the manufacturing process of the active substance.
•	04 June 2021	Change in the manufacturing process of the active substance.
•	26 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.