

VPA22020/006/001

Flubenol 5 % w/w Premix for Medicated Feeding Stuff

Variation	Summary	Date
Vet - C9	VNRA - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible - C9 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	30/05/22
B.II.d.1.d	IA - B.II.d.1.d - d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) - B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)	17/02/22
B.II.e.1.a.1	IA - B.II.e.1.a.1 - 1. Solid pharmaceutical forms - B.II.e.1.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	17/02/22
B.II.b.2.c.1	IAin - B.II.b.2.c.1 - 1. Not including batch control/testing - B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	17/02/22
B.II.b.2.a	IA - B.II.b.2.a - a) Replacement or addition of a site where batch control/testing takes place - B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place	17/02/22
B.II.b.2.a	IA - B.II.b.2.a - a) Replacement or addition of a site where batch control/testing takes place - B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place	17/02/22
B.II.b.2.a	IA - B.II.b.2.a - a) Replacement or addition of a site where batch control/testing takes place - B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place	17/02/22
B.II.b.1.a	IAin - B.II.b.1.a - a) Secondary packaging site - B.II.b.1.a -	17/02/22

	QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site	
B.II.b.1.b	IAin - B.II.b.1.b - b) Primary packaging site - B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site	17/02/22
B.II.b.1.e	IB - B.II.b.1.e - e) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products	17/02/22