VPA10387/059/003

Rimadyl Palatable Tablets 100 mg

Variation	Summary	Date
Vet - C9	VNRA - Vet - C9 - - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	14/08/26
Vet - F.II.c.3 z)	VRA-R - Vet - F.II.c.3 z) - - Vet - F.II.c.3 z) - Change in source of an excipient or reagent with TSE risk - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	07/08/26
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	17/07/26
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - - Vet - F.I.a.2 d) - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	30/03/26
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	12/12/25
Vet - B44 b)	VNRA - Vet - B44 b) - - Vet - B44 b) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient - New cerificate	03/12/25
Vet - F.II.f.1 c)	VRA-R - Vet - F.II.f.1 c) - - Vet - F.II.f.1 c) - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product	03/09/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	27/08/25
Vet - B12 b)	VNRA - Vet - B12 b) - b) Minor changes to an approved test procedure (starting material, excipient) - B12 b) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	25/03/25
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	24/03/25

Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	21/02/25
Vet - F.I.a.2 d)	VRA-R - Vet - F.I.a.2 d) - d) Minor change to the restricted part of an Active Substance Master File - F.I.a.2 d) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	21/02/25
Vet - B34	VNRA - Vet - B34 - Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product - B34 Changes to the quality part of the dossier: Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product	20/12/24
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	10/06/24
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	07/07/23
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	08/02/22
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	08/02/22
B.II.e.4.a	IA - B.II.e.4.a - a) Non-sterile medicinal products - B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	08/02/22