VPA10387/059/001

Rimadyl Palatable Tablets 20 mg

| Variation | Summary | Date |
|-------------------|---|----------|
| 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 | 10/06/24 |

| 1 | | |
|--------------|---|----------|
| | active substance - Substantial changes in the updated version of | |
| | the ASMF or the active substance part of the dossier | |
| 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 |