

VPA10815/046/003

**Zelys 10 mg chewable tablets for dogs**

| Variation            | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Date     |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Vet - C1             | VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 09/04/26 |
| Vet - C5             | VNRA - Vet - C5 - - Vet - C5 - Change in the pharmacovigilance system master file (PSMF) location                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 09/04/26 |
| Vet - A1 a)          | VNRA - Vet - A1 a) - - A1 a) Administrative changes - Change in the name or address of - the marketing authorisation holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 25/08/25 |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 02/09/24 |
| Vet - G.I.18         | VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 | 29/02/24 |
| Vet - B30 a)         | VNRA - Vet - B30 a) - a) Tightening of specification limits - B30 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: — tightening of specification limits                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 10/11/23 |
| Vet - F.II.f.1 a) 1. | VRA-R - Vet - F.II.f.1 a) 1. - a) Extension of the shelf life of the finished product 1. As packaged for sale (supported by real time data) - F.II.f.1 a) 1. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 03/05/23 |
| Vet - F.II.e.2 z)    | VRA-R - Vet - F.II.e.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.2 z) Quality Changes - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 22/03/23 |

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|  | variations outlined in section 6 and 7 of<br>EMA/CMDv/7381/2021 |  |
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