

VPA22020/065/001

**Baytril Flavour Tablets 15 mg**

| <b>Variation</b> | <b>Summary</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Date</b> |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 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 certificate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 02/09/25    |
| 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 | 09/07/25    |
| Vet - G.I.3 b)   | VRA-R - Vet - G.I.3 b) - b) Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon - G.I.3 b) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon                                                                                                                                                                                                                                                                    | 14/07/23    |
| Vet - B21        | VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 30/03/23    |
| Vet - B20        | VNRA - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product - B20 Changes to the quality part of the dossier: Replacement or addition of a primary packaging site of a non-sterile finished product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 30/03/23    |