

VPA22664/088/001

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle

| Variation | Summary | Date |
|-------------------|---|-------------|
| Vet - F.II.d.1 a) | VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range | 11/11/22 |
| Vet - B43 | VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible | 28/09/22 |
| Vet - B37 | VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product | 12/08/22 |
| Vet - B3 t) | VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient | 04/08/22 |
| B.I.z | II - B.I.z - z Other variation - B.I.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Other variation | 09/06/22 |