

VPA10981/015/001

CEFOKEL 50 mg/ml, suspension for injection for pigs and cattle

| Variation | Summary | Date |
|------------------|---|-------------|
| Vet - F.I.a.3 z) | VRA-R - Vet - F.I.a.3 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.3 z) Quality Changes - Active Substance - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 24/02/23 |
| Vet - F.I.b.2 z) | VRA-R - Vet - F.I.b.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.b.2 z) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 | 24/02/23 |
| 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) | 01/12/22 |
| Vet - C10 a) | VNRA - Vet - C10 a) - a) Administrative information concerning the holder's representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder's representative | 31/05/22 |