

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Reprocine 0.07 mg/ml Solution for Injection for Cattle and Pigs Vm 08007/4151

Change in the name of a quality control testing site in the manufacture of the active substance no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. (GB)
Addition of a manufacturer of the active substance or addition of a site of manufacture.
Change in distributor details from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northants, NN12 7LS, United Kingdom. Change of MAH from Vetoquinol S.A., Magny-vernois, 70200 LURE, France to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northants, NN12 7LS, United Kingdom.
Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
Introduction of a new pharmacovigilance system
Change of MAH, from VetCom-pharma GmbH to Vetoquinol S.A
Renewal.
Addition of a pack size.
Variation to change the address of the Marketing Authorisation Holder.
EUDE Renewal.
Repeat use.