

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

## **Post Authorisation Assessments**

## **Trimediazine Paste Oral Paste**

Vm 08007/4046

Change in the address of the marketing authorisation holder from Vetoquinol 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, Northamptonshire, NN12 7LS.
Addition of warning to Section 4.5 of the SPC "Not recommended in horses with known hypersensitivity, severe hepatic dysfunction or cardiac arrhythmias".
Grouped variation to update European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers.
Addition of a site of manufacture/assembly.
Deletion of a manufacturer.
Variation to change the batch release arrangements and quality control testing of the finished product.
Variation to make changes to the horse withdrawal period.
Renewal.
Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
Addition of a secondary assembler.
Change to the batch release arrangements.
Change of address of the Marketing Authorisation Holder.
Renewal.
Addition of a pack type.
Renewal.
Variation to update the licence particulars.
Change of company name.