

**Open study
(administration of a pharmaceutical product by a Veterinary Surgeon)**

Label (test article)

Test article name (or designation)
(Strength and active ingredient name) (Number of units or volume of contents)
For Veterinary Clinical Trial Use Only Keep Out of Reach of Children
(Species) (Route of administration) (Dose rate and frequency; <i>or cross –reference to trial protocol if this is complicated</i>) For investigation in the treatment of (.....)
Operator warnings: (.....)
Withdrawal period: (.....)
Return empty containers and unused material to the trial sponsor
(Storage conditions)
Batch number (...) Expiry date (...)
ATC holder (<i>name and address.....</i>) ATC number (...../.....)

General rule – applicable to all study types:

Where all of the suggested information cannot be included on the label, then the most important information must be included on the label and a cross-reference should be made to a package insert (written specifically for the purpose of that ATC) or to the outer carton if appropriate. The label for the outer packaging should also be supplied.

**Fully blinded study
(administration of a pharmaceutical product by a Veterinary Surgeon)**

Label (test article and placebo [or positive control])

Case Number (...)

May contain (... mg) of (*test article active substance name*) per (*unit e.g tablet*) [or (...mg) of (*positive control active substance name*) per (*unit*)]

(Number of units or volume of contents)

**For Veterinary Clinical Trial Use Only
Keep Out of Reach of Children**

(Species)

(Route of administration)

(Dose rate and frequency; *or cross-reference to trial protocol if this is complicated*)

For investigation in the treatment of (.....)

Operator warnings*: (.....)

Withdrawal period*: (.....)

Return empty containers and unused material to the trial sponsor

(Storage conditions*)

Expiry date (...)

ATC holder (*name and address*.....)

ATC number (...../.....)

*The most stringent warnings should be used e.g. longest withdrawal period

**Partially Blinded Study
(administration of a pharmaceutical product by a Veterinary Surgeon)**

Outer carton (treatment pack) contains either the test article or the positive control.

Label 1 – test article

Test article name (or designation)	
(Strength and active ingredient name) (Number of units or volume of contents)	
For Veterinary Clinical Trial Use Only Keep Out of Reach of Children	
(Species) (Route of administration) (Dose rate and frequency; <i>or cross –reference to trial protocol if this is complicated</i>) For investigation in the treatment of (.....)	
Operator warnings: (.....)	
Withdrawal period: (.....)	
Return empty containers and unused material to the trial sponsor	
(Storage conditions)	Batch number (...) Expiry date (...)
ATC holder (<i>name and address</i>)	
ATC number (...../.....)	

Label 2 – positive control

Test article name (or designation)	
(Strength and active ingredient name) (Number of units or volume of contents)	
For Veterinary Clinical Trial Use Only Keep Out of Reach of Children	
(Species) (Route of administration) (Dose rate and frequency; <i>or cross –reference to trial protocol if this is complicated</i>) For investigation in the treatment of (.....)	
Operator warnings: (.....)	
Withdrawal period: (.....)	
Return empty containers and unused material to the trial sponsor	
(Storage conditions)	Batch number (...) Expiry date (...)
ATC holder (<i>name and address</i>)	
ATC number (...../.....)	

Label 3 - Treatment pack label

Case Number (...)

Contains (... packs) of (*test article name*) or (...packs) of (positive control name)

**For Veterinary Clinical Trial Use Only
Keep Out of Reach of Children**

(Species)

Refer to the enclosed labelling for dosage instructions, operator warnings and withdrawal period.

For investigation in the treatment of (.....)

Return empty containers and unused material to the trial sponsor

(Storage conditions*)

Expiry date (...)

ATC holder (*name and address*.....)

ATC number (...../.....)

*Relevant to both trial materials