

Owner Consent Form

Test Article Information			
Study Name:	NeuroQuel™ (levamisole HCl tablet) for the control of signs of PNE (polyneuritis equi)	Study #:	219-FE-3.7.1
Test Article:	Levamisole HCl	Investigator:	
Formulation:	levamisole 550 mg oral tablet)	Species:	Equine
Treatment Claim:	for the control of signs of PNE (polyneuritis equi)		
Study Information			
Animal ID:	Horse name owner last name	Initials:	
Study Site:		Date:	
Owner Consent 219 FE 3.7.1			

Original copy retained by Investigator – signed copy provided to Owner

I, the owner, understand that this is an investigational pharmaceutical product (IVPP) for the control of clinical signs due to PNE (polyneuritis equi). The purpose of this study is obtaining effectiveness data for Food and Drug Administration’s licensing requirements. The above named IVPP has not been approved for sale in the United States for the claim being studied and it has not been subjected to testing for safety or efficacy. There is a risk of adverse reactions and unknown potential harm to a nursing foal or gestating fetus; hence, I am aware that there may be some risk associated with the use of this IVPP in a pregnant or lactating mare. If any of the following adverse events such as increased salivation, increased sensitivity or irritability, depression, diarrhea, colic, muscle tremors, ataxia (unsteady and uncoordinated movement), seizures, or collapse that occurs during the course of the study I will contact the Investigator. The horse should not receive acetylcholine esterase inhibitors (found in dewormers or fly products that include spray or feed-through products) during the study.

Furthermore, I understand that I am responsible to administer the IVPP and collect information regarding the animal’s health. I have made a fully informed decision regarding other diagnostic considerations and the use of the IVPP creates an obligation not to sell animals for food following treatment as noted in the protocol. I understand that I may remove my horse from this study at any time. I understand that I am responsible to return any unused medication to my veterinarian (Investigator) at the end of the study.

*Owner Name:		Phone #:	
Owner Address:		Fax #:	
City, State, Zip:		Email:	
Owner Signature:		Date:	

***Note:** In the absence of the owner, an authorized agent is permitted to give informed consent provided the above information has been discussed with the owner and the owner has given verbal consent to the authorized agent.

This form is to be completed prior to enrollment into the study.