

Owner Consent Form

Article Information			
Study Name:	NeuroQuel (levamisole HCl) for the control of signs of PNE (polyneuritis equi)	Study #:	219-FE-3.6
Test Article:	Levamisole HCl	Field Investigator:	Stacey, Huntington
Formulation:	NeuroQuel® (levamisole 550 mg tablet)	Species:	Equine
Treatment Claim:	For the control of signs of PNE (polyneuritis equi).		

Study Information			
Animal ID #:	24023 <i>Doc</i>	Initials:	
Study Site:	5429 S Farm Road 43 Billings 65610 sgfequine@gmail.com	Date:	

Owner Consent 219 FE 3.6

Original copy retained by Clinical Investigator - Certified copy provided to Owner

I, the owner, understand that this is an investigational pharmaceutical product (IVPP) for the control of clinical signs due to PE (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 nursing foal. 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 Field Investigator. The horse should not receive acetylcholine esterase inhibitors (found in anthelmintics 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.

*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.

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Clinical Investigator By:		Date:	
Reviewed By:		Date:	

Owner Observation Form 219 FE 3.6

Please do not administer any additional medications during the study.*

Animal ID #:	24023	Doc	Owner signature:
Study Site:	725		Date:

Animal Evaluation: Note any adverse reactions and number of tablets given

Day	Date Dose Given	Time Dose Given**	Normal Behavior	Normal Appetite	Normal Respiration	Colic or Diarrhea	Tablets (#) given, and first day of change. Estimate the amount of dose lost – leave blank if none.
1		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
2		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
3		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
4		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
5		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
6		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
7		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
8		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
9		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
10		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
11		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
12		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
13		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No
14		AM(±120 min)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	Dose: # given amount lost Is the horse better today? <input type="checkbox"/> Yes <input type="checkbox"/> No

***No additional medications should be used during the study unless prescribed as necessary by the Field Investigator such as pergolide (Precend®), ReguMate®, or thyroid medication.** Medications that include Firocoxib (Previcox or Equioxx), NSAIDS (such as phenylbutazone, aspirin, or flunixin), DMSO, or steroidal anti-inflammatory drugs should not be given during the study.

** Enter the time the medication was given in the box. Please give the medication at the same time every day. **Note:** Please return this form to the Investigator at the final examination.

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Clinical Investigator By:		Date:	
Reviewed By:		Date:	