

VETERINARIAN STUDY PARTICIPATION FORM

Date

Field Investigator contact information:
Study Site ID #

Study Monitor contact information:
Julie Osborne
Email: julieosborne@pathogenes.com

Study Participation for NeuroQuel® (levamisole HCl), 219-FE-3.6.

This study fulfills part of the FDA requirement for licensing NeuroQuel® (INAD 012219). NeuroQuel® is for the control of clinical signs of PNE (polyneuritis equi). NeuroQuel® is a compressed tablet composed of an immune modulator (levamisole HCl, 550 mg). The present study investigates the use of NeuroQuel® under field conditions. This study is a multiple site study.

I HAVE READ AND FULLY UNDERSTAND THE PROTOCOL BY SIGNATURE, I ACCEPT THE CONDITIONS STATED IN THE PROTOCOL AND AGREE TO ADHERE TO CONDUCT ALL ASPECTS OF THE STUDY AT , . (STUDY SITE)

Signature

Date

Sincerely,

Dr. Siobhan Ellison
Pathogenes, Inc.

Investigational Veterinary Pharmaceutical Product Form

Product Information

Product Name:	NeuroQuel®	Study# 219-FE-3.6	Lot #: EM116G18-1
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Field Investigator:	Study Site	Expiration: July 2020
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Note:	<p>This form accompanies the Investigational Veterinary Pharmaceutical Product (IVPP) shipment, please acknowledge receipt of this shipment by filling in the information in the first box below on the enclosed form. When the treatment period is completed and the IVPP inventory is reconciled please fill in the information in the second box below. Sign, date and return the form along with any unused IVPP to the Clinical Pharmacist (Pathogenes Inc).</p>
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Qty. Shipped:	14 tablets	Date Shipped:	
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Qty. Received:		Date Received:	
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Received By:		Date Signed:	
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Product Evaluation

Total Quantity (Units x Volume)	Used		Returned		Destroyed	
	Quantity	Date	Quantity	Date	Quantity	Date

*If any IVPP were destroyed, please note the reason and method of destruction:

Comments:	

**Submission Form
Day 0**

Field Investigator Information Study# 219-FE-3.6

Full Name:		Phone #:	
Address:		Fax #:	
City, State, Zip: ,		Email:	
Signature:	Study Site	Date:	

Animal Information

Animal ID:		Duration of deficit (days)	
Animal name			
Breed/AGE:	Sex:	<input type="checkbox"/> Mare <input type="checkbox"/> Stallion <input type="checkbox"/> Gelding	

Animal Evaluation Assign a Clinical Score by checking the appropriate box:

Assigned Clinical Score: *Enter the single value that best describes the clinical signs for each of the 6 categories below: 0= no abnormal signs; 1=mild signs; 2=moderate signs; 3=severe signs*

Muscle tone: tongue tone, anus, perianal region, or urethral sphincter show decreased or absent muscle tone	CLINICAL SCORE
Sensitivity: Rubs tail; anal sphincter reflex decreased or decreased peri-anal region sensitivity; gluteal muscle, semitendinosus muscle, or semimembranosus muscle shows abnormal sensitivity; increased/decreased panniculus response	CLINICAL SCORE
Paresis or paralysis: Penis or urinary bladder resulting in abnormal urination or dribbling urine; masticatory muscles, facial muscle or tongue resulting in dysphagia or dropping feed; tail carried to one side; pelvic limb weakness resulting in mild ataxia	CLINICAL SCORE
Muscle atrophy or fasciculation: Top line decreased musculature; gluteal muscle, semitendinosus muscle, semimembranosus muscle, masticatory muscles, facial muscles atrophied or show fasciculations; fasciculation of supporting muscles when rear limb elevated; generalized muscle fasciculations	CLINICAL SCORE
Gait anomaly: Proprioceptive deficits, weakness on tail pull	CLINICAL SCORE
Cranial nerve signs: Abnormal behavior; vestibular nystagmus; head tilt or eye drop; asymmetric twist to lips	CLINICAL SCORE

Treatment History

Was this animal treated previously?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is this a relapse of clinical signs?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, indicate treatment		
If Yes, enter treatment date:	Date Started:	Date Ended:
If Yes, enter dosage and duration:	Dosage:	Duration:
Was levamisole HCl used in this	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Physical Examination

Respirations:	/ breaths per minute	Pulse:	/ beats per min	Temperature:	/ °F
Weight (lbs):	Dose: One half tablet is given to a horse weighing 605 pounds to 880 pounds, 1 tablet to a horse weighing 881-1210 pounds, 1 ½ tablets to a horse weighing 1211-1815 pounds, and/or 2 tablets to a horse that is over 1815				

Circle the number of tablets to be given once daily to this horse based on weight obtained by weight tape.

½ tablet 1 tablet 1 ½ tablets 2 tablets

Horses receiving NeuroQuel® should not receive any products that contain cholinesterase inhibitors. Please do not give Vitamin E during the study.

Overall condition of animal:	<input type="checkbox"/> Good = outward appearance and physical examination is normal.
	<input type="checkbox"/> Fair = abnormal findings on physical examination suggestive of systemic disease in addition to PNE.
	<input type="checkbox"/> Poor = horse appears to be debilitated

Animal Evaluation

Mark the appropriate response below.

1. Can this horse be medicated orally?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2. Are the skin and eyes normal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. Is the cardiovascular system normal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4. Is the gastrointestinal system normal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
5. Is the cranial nerve assessment normal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
6. Is the respiratory system normal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
7. Is the genitourinary system normal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

Comments:

Animal Evaluation supporting diagnosis of PNE

Test Description	Test or exam Completed?	Test Date	Test Result	Comments
Neurological exam	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Abnormal <input type="checkbox"/> Normal	
MPP/MP2 ELISA	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Positive <input type="checkbox"/> Negative	
Recent history trauma?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Respiratory infection within 10 days of exam?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Has the horse been vaccinated against EHV-1	<input type="checkbox"/> Yes <input type="checkbox"/> No		Has the horse been vaccinated against rabies?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Antibody against <i>S. neurona</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
If not supplemented with Vitamin E, what is the serum level?	_____ $\mu\text{g/ml}$ NA	NA because horse receives oral Vitamin E.

Eligibility: Inclusion Criteria INCLUDE Yes No

1. Has this animal met the signalment criterial listed in Section 8.1 of the protocol? Yes No
2. Does this animal have a presumptive diagnosis of polyneuritis equi supported by Clinical Score? Yes No
3. Is this animal seronegative for *S. neurona* antibodies? Yes No
4. Are signs unrelated to recent trauma? Yes No
5. Are signs unrelated to respiratory infection in the last 10 days
6. or horse is vaccinated for EHV-1 Yes No
7. Has rabies been ruled out by clinical examination or clinical history? Yes No
8. The Vitamin E level is within normal limits? Yes No

Any "No" answer makes the animal ineligible for participation in this study.

Exclusion Criteria

9. Has the horse met the inclusion criteria? Yes No
10. Answer no if the horse is currently enrolled in another study or owned by study personnel? Yes No
11. Answer no if this animal has clinical signs of disease other than polyneuritis equi. Yes No
12. Answer no if signs of PNE absent or the animal is recumbent. Yes No
13. Answer no if the animal received phenylbutazone or flunixin, DMSO, or steroidal anti-inflammatory drugs in the past 3 days or history of treatment with levamisole HCl? Yes No
14. Is the horse seropositive for antimyelin protein antibody? Yes No
15. Can the client/owner anticipate treat the horse for 14 days? Yes No

Any "No" answer makes the animal ineligible for participation in this study.

Sample Collection

Day	Sample Date	Sample Time	Sample Type				Initials
0			<input type="checkbox"/> Red Top	<input type="checkbox"/> Red Top	<input type="checkbox"/> Purple Top	<input type="checkbox"/> Purple Top	

Note: Record the Sample Date, Sample Time, and Sample Type when the sample collection is drawn. Initial the entry.

Clinical Pathology Parameters for Blood	
Serum	EDTA blood
• Alkaline phosphatase	• Complete Blood Count
• Total bilirubin	• Red Cell Count
• Aspartate aminotransferase	• Packed Cell Volume (PCV)
• Gamma glutamyl transferase	• Hemoglobin
• Urea nitrogen	• Mean Corpuscular Volume (MCV)
• Creatinine	• Mean Corpuscular Hemoglobin (MCH)
• Total protein	• Mean Corpuscular Hemoglobin Concentration (MCHC)
• Albumin	• Platelet Count

• Globulin and A/G (albumin/globulin) ratio (calculated)	• Leukocyte Count
• Glucose	• Leukocyte Differential
• Electrolytes (sodium, potassium, chloride)	• RBC Morphology
• Calcium	
• Phosphorus	

Please ship 2 red top and 1 purple top tube to: (a) the Test facility diagnostic laboratory and (b) Pathogenes Inc.

DAY 14 Evaluation Form

Field Investigator Information Study #219-FE-3.6

Full Name:		Phone #:	
Address:		Fax #:	
City, State, Zip:		Email:	
Signature:	Study Site #	Date:	

Animal Information

Animal ID:			
Animal name			

Animal Evaluation

Assigned Clinical Score: *Enter the single value that best describes the clinical signs for each of the 6 categories below: 0= no abnormal signs; 1=mild signs; 2=moderate signs; 3=severe signs*

Muscle tone: tongue tone, anus, perianal region, or urethral sphincter show decreased or absent muscle tone	CLINICAL SCORE
Sensitivity: Rubs tail; anal sphincter reflex decreased or decreased peri-anal region sensitivity; gluteal muscle, semitendinosus muscle, or semimembranosus muscle shows abnormal sensitivity; increased/decreased panniculus	CLINICAL SCORE
Paresis or paralysis: Penis or urinary bladder resulting in abnormal urination or dribbling urine; masticatory muscles, facial muscle or tongue resulting in dysphagia or dropping feed; tail carried to one side; pelvic limb	CLINICAL SCORE
Muscle atrophy or fasciculation: Top line decreased musculature; gluteal muscle, semitendinosus muscle, semimembranosus muscle, masticatory muscles, facial muscles atrophied or show fasciculations; fasciculation of	CLINICAL SCORE
Gait anomaly: Proprioceptive deficits, weakness on tail pull	CLINICAL SCORE
Cranial nerve signs: Abnormal behavior; vestibular nystagmus; head tilt or eye drop; asymmetric twist to lips	CLINICAL SCORE

Physical Examination

Respirations:	/ breaths per minute	Pulse:	/ beats per min	Temperature:	/ °F
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Circle the number of tablets THAT WERE GIVEN once daily to this horse.

½ tablet 1 tablet 1 ½ tablets 2 tablets

Overall condition of animal: **Good** = outward appearance and physical examination is normal.

Fair = abnormal findings on physical examination suggestive of systemic disease in addition to PNE.

Poor = horse appears to be debilitated

Animal Evaluation

Mark the appropriate response below.

8. Was this horse medicated orally? Yes No N/A
9. Are the skin and eyes normal? Yes No N/A
10. Is the cardiovascular system normal? Yes No N/A
11. Is the gastrointestinal system normal? Yes No N/A
12. Is the cranial nerve assessment normal? Yes No N/A
13. Is the respiratory system normal? Yes No N/A
14. Is the genitourinary system normal? Yes No N/A

Comments:

Clinical Pathology Parameters for Blood		
Serum	EDTA blood	
• Alkaline phosphatase	• Complete Blood Count	
• Total bilirubin	• Red Cell Count	
• Aspartate aminotransferase	• Packed Cell Volume (PCV)	
• Gamma glutamyl transferase	• Hemoglobin	
• Urea nitrogen	• Mean Corpuscular Volume (MCV)	
• Creatinine	• Mean Corpuscular Hemoglobin (MCH)	
• Total protein	• Mean Corpuscular Hemoglobin Concentration (MCHC)	
• Albumin	• Platelet Count	
• Globulin and A/G (albumin/globulin) ratio <small>(calculated)</small>	• Leukocyte Count	
• Glucose	• Leukocyte Differential	
• Electrolytes (sodium, potassium, chloride)	• RBC Morphology	
• Calcium		
• Phosphorus	Please ship 1 red top and 1 purple top tube to: (a) the Test facility diagnostic laboratory	