



The unique DNA immunostimulant that jump-starts the animal's own defense system to help fight BRD.

ZelNate® is the first licensed immunostimulant that aids in the treatment of Bovine Respiratory Disease (BRD) due to *Mannheimia haemolytica*. ZelNate jump-starts the animal's own defense system to help fight infectious disease.

ZelNate benefits

- Aids in the treatment of BRD due to *Mannheimia haemolytica* in cattle 4 months of age or older when administered at the time of, or within 24 hours after, a perceived stressful event
- In six studies, ZelNate was shown to significantly reduce mortality due to BRD from 4.45% to 3.5% or a relative change of 20.83% when compared to the control group¹
- Unique DNA liposome complex stimulates the innate immune system in cattle
 - The innate immune system has been shown to provide a rapid, potent and broad protective response to infectious agents
- A novel technology that enhances an animal's natural defenses and contains no antibiotics and no preservatives
 - Can be used in natural programs for effective BRD management
 - When compared to antimicrobial metaphylaxis therapy in cattle at medium risk of developing BRD, ZelNate performed in a comparable fashion and was observed to be non-inferior to antimicrobials²
- Available in 10 and 50 dose package sizes

How to administer ZelNate

- Intramuscular (IM) administration:
 - No injection site issues were observed during field safety studies
- Intranasal administration:
 - Spray into one nostril with a syringe using an atomization tip



As part of a broad BRD management portfolio that includes vaccines and anti-infectives, ZelNate is supported by Elanco technical consultants who can help your business maximize the product's value

For more information, contact your veterinarian or Elanco sales representative.

Do not administer within 21 days of slaughter.

¹Nickell J, Keil D, Settje T, et al. Efficacy and safety of a novel DNA immunostimulant in cattle. *Bov Pract.* 2016. 50(1):9-20.

²Elanco Animal Health. Data on File.

This product is based on technology developed by Juvaris BioTherapeutics and is patent protected. Animal health applications are being developed exclusively under the rights of Elanco and are protected by patents.

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Right for cattle. Right by you.

Elanco

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See productdata.aphis.usda.gov for a summary of the studies approved by the USDA for licensing this product. This package insert may also contain additional information developed by the licensee.

DNA Immunostimulant



For Intramuscular or Intranasal Administration to Cattle

FOR VETERINARY USE ONLY

02337

READ IN FULL DESCRIPTION

The innate immune system in cattle has been shown to provide a potent, rapid, nonspecific, protective response to infectious agents, such as *Mannheimia haemolytica* that can lead to Bovine Respiratory Disease (BRD). BRD is a serious condition that commonly causes lung lesions, reduced lung capacity and mortality.

ZELNATE® is a bacterial-produced plasmid DNA with a liposome carrier that stimulates the innate immune system and has been shown to be effective against bovine respiratory disease due to *Mannheimia haemolytica*.

The freeze-dried (desiccate) product is packaged with two different sterile diluents. The First Sterile Rehydrator (vial 1) is used to reconstitute the desiccate cake (vial 2), and then transferred to the Final Sterile Solution (vial 3) to achieve the proper concentration for administration.

INDICATION

This product has been shown to be effective for the treatment of cattle, 4 months of age or older, against bovine respiratory disease due to *Mannheimia haemolytica*. For more information regarding efficacy and safety data, see productdata.aphis.usda.gov.

This product has been shown to be effective at the time of, or within 24 hours after, a perceived stressful event.

IMPORTANT STORAGE CONDITIONS

Store Refrigerated

2°C to 8°C (35°F to 46°F)

DO NOT FREEZE.

Stability has been demonstrated for at least 8 hours after reconstitution if vial is refrigerated and sterility is maintained.

Individual Study Summary - Study# 200270

Study Type	Efficacy																		
Pertaining to	<i>Mannheimia haemolytica</i>																		
Study Purpose	Efficacy against bovine respiratory disease																		
Product Administration	One dose administered by IM route at the time of challenge. Control group administered diluent only																		
Study Animals	64 Holstein steers of 3-4 months of age; randomized into 2 groups of 32 calves each																		
Challenge Description	live <i>M. haemolytica</i> inoculum																		
Interval observed after challenge	Observed daily for 5 days. Lungs were evaluated 5 days after challenge.																		
Results	<p>The percent of lung mass that was abnormal (consolidated) was calculated/scored for every animal. For animals that died prior to Day 5, the necropsy lung score was not included in the analysis.</p> <p>5 number summary for lung consolidation</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>0%</td> <td>6%</td> <td>10%</td> <td>15%</td> <td>33%</td> </tr> <tr> <td>Treated</td> <td>0%</td> <td>1%</td> <td>4%</td> <td>10%</td> <td>22%</td> </tr> </tbody> </table> <p>Raw data shown on the table below. The animals that died prior to Day 5 are marked with an asterisk (*).</p> <p>The deaths prior to Day 5 were: 1/32 in Treated group; 1/32 in Control group. Diagnosis was severe bovine respiratory disease for calf in Control group.</p>	Treatment	Minimum	Q1	Median	Q3	Maximum	Controls	0%	6%	10%	15%	33%	Treated	0%	1%	4%	10%	22%
Treatment	Minimum	Q1	Median	Q3	Maximum														
Controls	0%	6%	10%	15%	33%														
Treated	0%	1%	4%	10%	22%														
USDA Approval Date	28-Feb-2013																		

Lung consolidation scores (%), in order to rank:

Treated	0%	0%	1%	1%	1%	1%	1%	1%	2%	2%	3%	3%	3%*	4%	4%	4%
Control	0%	0%	3%	3%	3%	4%	6%	6%	6%	7%	7%	7%	8%	8%	10%	10%
Treated (Cont.)	4%	5%	5%	6%	8%	9%	10%	10%	10%	11%	12%	13%	13%	15%	18%	22%
Control (Cont.)	10%	10%	10%	11%	13%	14%	15%	15%	18%	18%	21%	23%	27%	29%	33%	34%*

* death prior to Day 5

METHOD OF ADMINISTRATION

Inject 2 mL intramuscularly at the time of, or within 24 hours after, a perceived stressful event (for example: weaning, shipping, commingling or adverse environmental conditions). Alternatively, spray 2 mL into one nostril using an atomization tip attached to the syringe; the atomizer should produce a fine mist of particles 30-100 microns in size for delivery to the mucosal membranes.

CAUTION

In case of human exposure, contact a physician. Use entire contents when first opened. Inactivate unused contents before disposal.

PRECAUTION

Do not administer within 21 days of slaughter. Do not mix with other products, except as specified on this label. This product has not been tested in pregnant animals.

OTHER INFORMATION

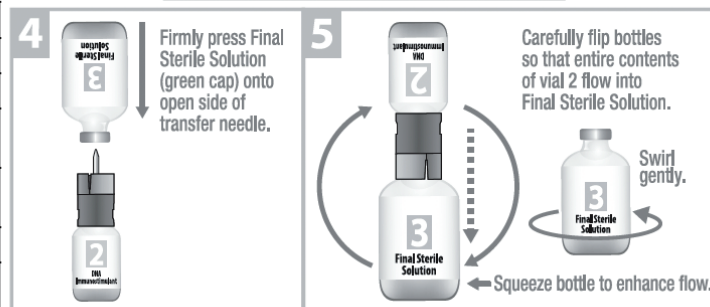
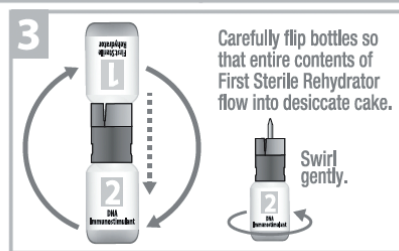
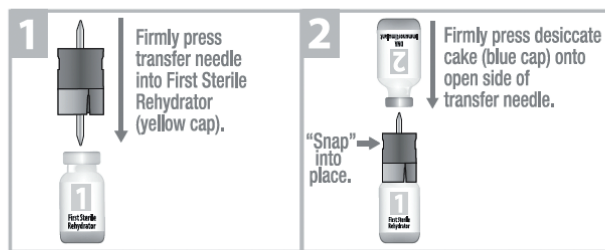
Contains no antibiotics and no preservatives.

HOW SUPPLIED

Vials of 10 and 50 doses.



Mixing process must be completed in the appropriate order. Transfer needle must be fully inserted to prevent spillage.



DIAMOND

MANUFACTURED BY:
Diamond Animal Health, Inc.
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U.S. Veterinary License No. 213
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