ZELNATE®

TECH SHEET

ZELNATE® DNA IMMUNOSTIMULANT

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.

- 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%.[1]
- IM (intramuscular) administration
  - No injection site issues were observed during field safety studies.
- Intranasal administration
  - Spray into one nostril with a syringe using an atomization tip.
- Proprietary DNA liposome complex stimulates the innate immune system in cattle.
  - The innate immune system has been shown to provide a rapid, potent and broad protectective 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.
- Available in 10 and 50 dose package sizes.

FOR MORE INFORMATION, PLEASE CONTACT YOUR ELANCO SALES REPRESENTATIVE OR CALL US AT 800-364-2014.

Do not administer within 21 days of slaughter.

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

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.

Elanco™

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

ZELNATE®

For Intramuscular or Intranasal Administration to Cattle

FOR VETERINARY USE ONLY

02320

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.

Bayer

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. Use entire contents of vial once first opened.

CAUTION

In case of human exposure, contact a physician.

Individual Study Summary - Study# 200270

Study Type	Efficacy
Pertaining to	*Mannheimia haemolytica*
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 *M. haemolytica* inoculum
Interval observed after challenge	Observed daily for 5 days. Lungs were evaluated 5 days after challenge.
Results	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. 5 number summary for lung consolidation **Treatment** **Minimum** **Q1** **Median** **Q3** **Maximum** Controls 0% 6% 10% 15% 33% Treated 0% 1% 4% 10% 22% Raw data shown on the table below. The animals that died prior to Day 5 are marked wi an asterick (*). 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.
USDA Aproval 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**

DIAMOND

BAYER

MANUFACTURED BY:
Diamond Animal Health, Inc.
Des Moines, IA 50327
U.S. Veterinary License No. 213
PCN 9381.D0
Made in U.S.A.
November, 2018
85877690 LV1811

DISTRIBUTED BY:
Bayer HealthCare LLC,
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201 U.S.A.
1-800-633-3796

This product is based on technology developed by Juvaris BioTherapeutics and is patent protected. Animal health applications are being exclusively developed by Bayer HealthCare, Animal Health Division and are the subject of Bayer patent applications.

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.

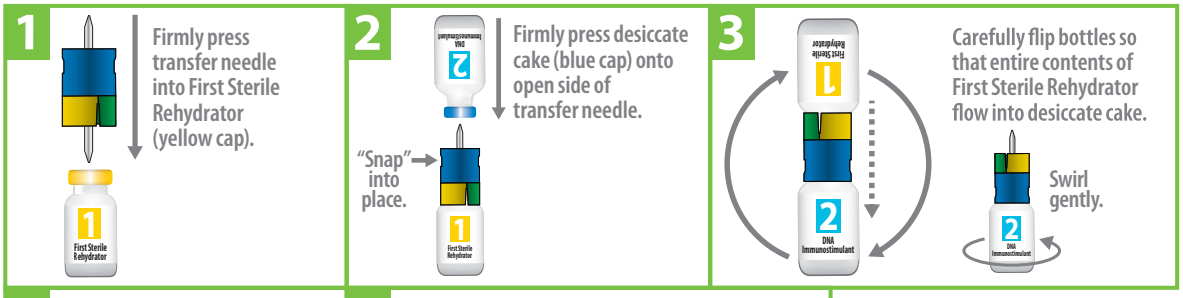
OTHER INFORMATION

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.



ZELNATE® is ready for use.

Signature Page for PM-US-21-0759 v1.0

PMO Approval	Marissa Streitmatter Material Owner 03-Aug-2021 19:29:11 GMT+0000

Regulatory Approval	Debra Walton Regulatory 04-Aug-2021 12:07:07 GMT+0000

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