DNA Immunostimulant

ZELNATE™

For Intramuscular Administration to Cattle

FOR VETERINARY USE ONLY 02293

READ IN FULL

DESCRIPTION

ZELNATE™ is a bacterial-produced plasmid DNA with a liposome carrier that stimulates the innate immune system in cattle. The innate immune system has been shown to provide a potent, rapid, nonspecific, protective response to infectious agents, such as those that can lead to Bovine Respiratory Disease (BRD). BRD is a serious condition that commonly causes lung lesions, reduced lung capacity and mortality.

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

ZELNATE™ is indicated for use as an aid in the treatment of Bovine Respiratory Disease 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.

IMPORTANT STORAGE CONDITIONS

Store Refrigerated
2°C to 8°C (35°F to 46°F)
DO NOT FREEZE.

STUDY DATA

In Study A, 3- to 4-month-old steers were randomly allocated to receive either ZELNATE™ or a negative control (N=32 per group). On Day 0, each group of healthy calves was intramuscularly administered their respective treatment and challenged (intratracheally) with *Mannheimia haemolytica*. Lung lesion scores were obtained on Day 5. ZELNATE™ significantly ($p<0.05$) reduced lung lesion scores compared to the control group (Figure A).[1]

In Study B, 3- to 4-month-old steers were randomly allocated to receive either ZELNATE™ or a negative control (N=40 per group). On Day 0, each group was challenged (intratracheally) with *Mannheimia haemolytica*. Twenty four hours post-challenge (i.e., Day 1), BRD morbidity was observed to be 67.5%. At this time, each group was intramuscularly administered their respective treatment (i.e., in the face of clinical BRD). Lung lesion scores were obtained on Day 5. Among calves that lived until Day 5, ZELNATE™ numerically reduced lung lesion scores compared to the control group (data not shown). The cumulative incidence of death, associated with BRD, was 11.3%. The lung lesion scores among dead calves and those living to Day 5 were observed to be 55.3% and 17.6%, respectively. ZELNATE™ significantly ($p<0.05$) reduced mortality compared to the control group (Figure B).[2]

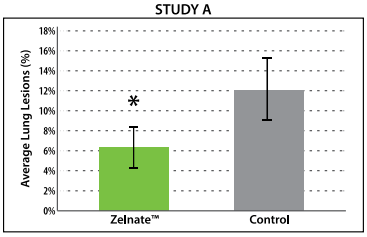


Figure A: Average lung lesion scores between calves receiving either ZELNATE™ or a negative control at the same time as an intratracheal *Mannheimia haemolytica* challenge. Lung lesion scores reflect those observed on Day 5 post-challenge.

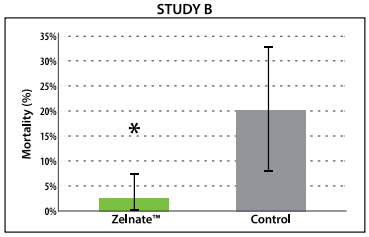


Figure B: Cumulative incidence of mortality between calves receiving either ZELNATE™ or a negative control 24 hours after an intratracheal *Mannheimia haemolytica* challenge. Mortality estimates reflect those observed from the Day of challenge (Day 0) to Day 5 post-challenge.

* = statistically significant reduction ($p<0.05$)

In conclusion, ZELNATE™, as a stand-alone therapy, has been shown to: 1) significantly reduce lung lesion scores associated with BRD when administered in the face of disease challenge (Study A), and 2) significantly reduce the risk of mortality when administered in the face of clinical BRD (Study B).

[1]Data on file. Bayer HealthCare Animal Health.
[2]Data on file. Bayer HealthCare Animal Health.

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). Use entire contents of vial once first opened.

PRECAUTION

Do not administer within 21 days of slaughter.

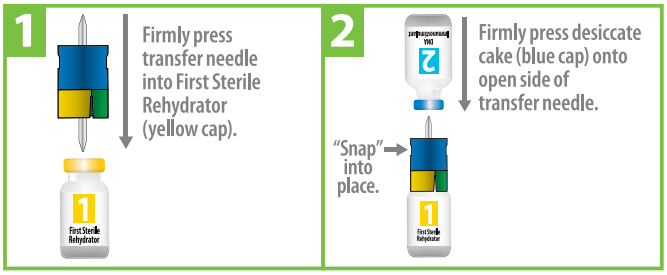
OTHER INFORMATION

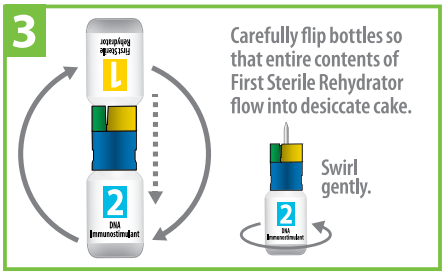
Contains no antibiotics and no preservatives.
ZELNATE™ has shown no detectable lesions at the site of intramuscular injection.

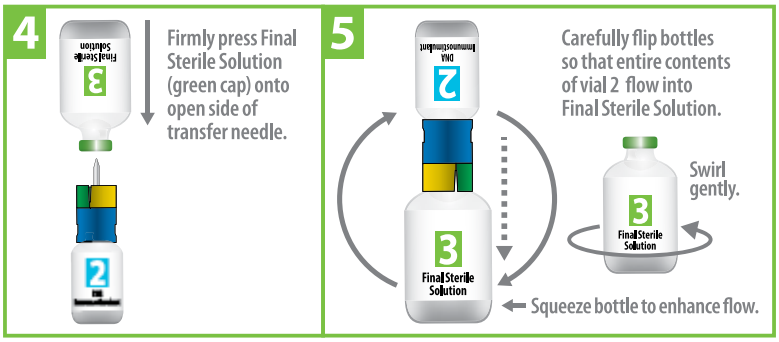
HOW SUPPLIED

Vials of 5, 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.

DIAMOND

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Diamond Animal Health, Inc.
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Made in U.S.A.

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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 and are protected by Bayer patent applications.

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