

Date of Approval: **NOV 15 2007**

## FREEDOM OF INFORMATION SUMMARY

### SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 012-123

GALLOMYCIN-100

Erythromycin  
Solution for Injection  
Cattle

Effect(s) of Supplement: Provide for the codification of the 100 mg product with the DESI- finalized claims in cattle.

Sponsored by:

Cross Vetpharm Group Ltd.

2007-12-123

FOIS 2

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**I. GENERAL INFORMATION:**

- A. File Number:** NADA 012-123
- B. Sponsor:** Cross Vetpharm Group Limited  
Broomhill Road  
Tallaght, Dublin 24  
Ireland
- Drug Labeler Code: 061623
- U.S. Agent: Linda M. Duple  
2836 Dolliver Park Avenue  
Lehigh, IA 50557
- C. Proprietary Name(s):** GALLIMYCIN-100
- D. Established Name(s):** Erythromycin
- E. Pharmacological Category:** Antibacterial
- F. Dosage Form(s):** Solution for injection
- G. Amount of Active Ingredient(s):** 100 mg/mL
- H. How Supplied:** 100 mL multiple-dose, rubber-stoppered vials
- I. How Dispensed:** OTC
- J. Dosage(s):** Administer 4 mL/100 lbs. body weight (4mg/lb) once daily for up to 5 days.
- K. Route(s) of Administration:** Intramuscular
- L. Species/Class(es):** Cattle
- M. Indication(s):** For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasturella multocida* organisms susceptible to erythromycin.
- N. Effect(s) of Supplement:** This supplement will provide for the codification of the 100 mg product with the DESI- finalized claims in cattle.

## **II. EFFECTIVENESS:**

### **A. Dosage Characterization:**

This supplemental approval does not change the previously approved dosage or dosage range. The FOI Summary for the original approval of NADA 012-123 (see attachment) dated June 30, 1993, contains dosage characterization information for cattle.

### **B. Substantial Evidence:**

#### **1. Type of Study (i.e., Dose Confirmation, Clinical Field Study, Pharmacokinetics, Microbiology, etc.)**

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 012-123 (see attachment) dated June 30, 1993, contains a summary of studies that demonstrate effectiveness of the drug for cattle.

## **III. TARGET ANIMAL SAFETY:**

### **A. Type of Study (i.e., Tolerance Study, Toxicity Study, Injection Site Irritation Study, Reproductive Safety, etc.)**

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 012-123 (see attachment) dated June 30, 1993, contains a summary of studies that demonstrate effectiveness of the drug for cattle.

## **IV. HUMAN FOOD SAFETY:**

### **A. Toxicology:**

CVM did not require toxicology studies for this supplemental approval. The FOI Summary for the original approval of NADA 012-123 (see attachment) dated June 30, 1993, contains a summary of all toxicology studies.

### **B. Residue Chemistry:**

CVM did not require residue chemistry studies for this supplemental approval. The FOI Summary for the original approval of NADA 012-123 dated June 30, 1993, contains a summary of residue chemistry studies for cattle.

**C. Microbial Food Safety:**

Not applicable

**D. Analytical Method for Residues:**

The FOI Summary for the original approval of NADA 012-123 dated June 30, 1993, contains the analytical method summaries for erythromycin in cattle.

**V. USER SAFETY:**

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to GALLIMYCIN-100:

**KEEP OUT OF REACH OF CHILDREN**

**VI. AGENCY CONCLUSIONS:**

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514. The data demonstrate that GALLIMYCIN-100, when used according to the label, is safe and effective for the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasturella multocida* organisms susceptible to erythromycin. Additionally, data demonstrate that residues in food products derived from cattle treated with GALLIMYCIN-100 will not represent a public health concern when the product is used according to the label.

**A. Marketing Status:**

This product has been approved for OTC marketing status. For more details on the basis for the decision see original FOI Summary dated June 30, 1993 (attached).

**B. Exclusivity:**

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

**C. Supplemental Applications:**

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR §514.106(b)(2)).

**D. Patent Information:**

The sponsor did not submit any patent information with this application.

**VII. ATTACHMENTS:**

Original NADA 012-123 FOI Summary

Facsimile Labeling: GALLIMYCIN-100 (100mg/mL) 100 mL vial label

HFV-102

FREEDOM OF INFORMATION SUMMARY

JUN 30 1993

I. GENERAL INFORMATION

A. NADA 12-123

B. Name and Address of Sponsor:

Sanofi Animal Health, Inc.  
7101 College Blvd., Suite 610  
Overland Park, KS 66210

C. Generic Name of Drug:

Erythromycin

D. Trade Name of Drug:

GALLIMYCIN (Erythromycin) INJECTION, 200 mg/mL

E. Marketing Status:

OTC

F. Effect of Supplements:

One supplemental application is a Category II change in dosage which was initiated in order to bring the drug product into compliance with the National Academy of Science/National Research Council - Drug Efficacy Study Implementation (NAS/NRC/DESI) recommendations.

The other supplemental application is a Category II change in tolerance for drug residues from zero to 0.1 ppm for beef tissues.

II. INDICATIONS FOR USE:

Indicated for bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with Pasteurella multocida susceptible to erythromycin.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGES

A. Sterile solution

B. Intramuscular injection only

C. 4 mg/pound body weight (2 mL/100lbs) once daily up to 5 days

IV. EFFECTIVENESS: NADA 12-123 was originally approved as safe for use as labeled on March 22, 1960. The drug was the subject of National Academy of Sciences/National Research Council/Drug Efficacy Study Implementation (NAS/NRC DESI) reports which were published in the FEDERAL REGISTER of August 18, 1970: The Academy evaluated these products as probably effective in the treatment of certain diseases in cattle, sheep, swine, horses, dogs, cats, chickens, and turkeys.

The Academy stated:

- a. Each disease claim should be properly qualified "appropriate for use (name of disease) caused by pathogens sensitive to (name of drug)", and if the disease claim cannot be so qualified the claim must be dropped.
- b. Claims made regarding "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of."
- c. The dosage in large animals and frequency of administration in all species need to be documented - the dosage should be expressed on the basis of milligrams of erythromycin per pound of body weight.
- d. The resistance statement and statements claiming more effectiveness than other microbial agents need to be deleted.
- e. Certain items in the labeling need revision, including withdrawal times, cautions, misleading association of sensitivity statement and certain diseases and the recommended use as an aid in curtailing weight losses due to handling and transporting cattle.

- f. Directions for use should provide for administering the preparation with sterile equipment.
- g. Directions for lay use are inadequate.

The Food and Drug Administration concurs with the Academy's findings; interpreting the phrase "...cannot be so qualified ..." in paragraph (a.) to mean "...is not supported by adequate data...". FDA then proceeded to review all available data relating to the effectiveness of products subject to NADA 12-123 to determine which label claims were supported by the requisite proof of effectiveness. That review resulted in a letter dated January 21, 1976, addressed to the firm, in which the agency stated that it had concluded that data supported effectiveness for the treatment of bovine respiratory disease only.

Thereafter, the sponsor complied with the evaluation of NAS/NRC and the FDA's conclusions in the following manner:

1. The disease claim has been qualified as to the causative pathogen which is susceptible to erythromycin. All other disease claims and several animal species have been deleted from the indications for use.
2. The labeled indications have been revised to read, "For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia)..." instead of "Is indicated for prompt and effective treatment of conditions resulting from infections caused by organisms..."

3. The dosage and frequency of administration in cattle has been documented. On January 21, 1976, the Center for Veterinary Medicine determined the efficacy portion of the application to be complete by virtue of the fact that bioavailability and comparability data submitted adequately demonstrated that sufficient drug levels were maintained at a dosage of 4 mg per pound body weight administered daily for up to 5 days.
4. The labeling has been revised to delete the resistance statement and statements claiming more effectiveness.
5. The labeling has been revised to include appropriate withdrawal times and cautions, and to delete the other items mentioned above.
6. The directions for use have been revised to include the precautions to administer the preparation with sterile equipment.
7. Adequate directions for lay use for administering this drug by the intramuscular route are included.

V. ANIMAL SAFETY;

NADA 12-123 was originally approved as safe on March 22, 1960. Safety of this product is also substantiated by the absence of any adverse effects reported in three new studies: a bioequivalency study, and the treatment periods of a milk residue study and a tissue residue study.

During these three studies, 24 animals were given two separate injections 14 days apart, five animals were given three consecutive daily injections and 18 animals were given five consecutive daily injections. The injections were given intramuscularly in the leg or neck at a dose of 4 mg/lb. body weight. Transient reactions such as injection site swelling were observed over a few days following these injections, but no evidence of hemorrhage, fibrosis, or necrosis was externally observable.

Gross histopathological examination was made of tissues at and surrounding the injection site following intramuscular injections to 18 cattle of 6.5 ml to 8.8 mL/site of GALLIMYCIN INJECTION. These animals were each given a single daily injection for five days. Three animals per time period were then sacrificed at 6, 12, 18, 24, 36, and 48 hours post-last dose (injection #5). Injection site #3 was excised for examination. Gross inspection revealed that injection site lesions were variable in size with approximate average dimensions of 1.25 cm diameter X 2.9 cm deep. Injection site lesions were characterized by a central core of muscle tissue, tan-gray to gray in color and surrounding this central area of discoloration was a dark red zone of more normal-appearing muscle with obvious areas of hemorrhage. Histopathological examination revealed a central core of acutely necrotic muscle fibers. Surrounding this central core was a zone of muscle fibers in various stages of degeneration characterized by mineralization of the sarcoplasm. Livers and kidneys were examined grossly and histopathologically with no unusual or unexpected observations reported.

Results of these studies indicate that a cautionary label statement concerning the trimming of cattle tissues during the dressing process is necessary based on the withdrawal period for the product.

VI. HUMAN FOOD SAFETY:

A. Name and Address of Investigator:

Bio-Labs, Inc.  
132 Las Cruces Ave.  
Las Cruces, New Mexico 88001  
Dr. John H. Kinzell

B. Tissue Residue Depletion Studies:

A single tissue residue depletion study was conducted in cattle to determine the residues of erythromycin following the administration of GALLIMYCIN INJECTION. The dosage regimen was: intramuscular injection at 4 mg/lb. of body weight for five consecutive days. Residue determinations were made at 6, 12, 18, 24, 36 and 48 hours post last-dose. Three animals were sacrificed at each time period and tissues were excised for erythromycin assay.

Table 3.

ERYTHROMYCIN RESIDUES IN TISSUES (PPM)

<u>Hours Post Injection</u>	<u>Kidney</u>	<u>Liver</u>
6	1.90 ( $\pm$ 0.39)*	6.13 ( $\pm$ 4.36)
12	2.90 ( $\pm$ 1.05)	3.88 ( $\pm$ 3.14)
18	1.03 ( $\pm$ 0.54)	4.31 ( $\pm$ 2.68)
24	0.89 ( $\pm$ 0.81)	0.82 ( $\pm$ 0.69)
36	0.18 ( $\pm$ 0.07)	0.12 ( $\pm$ 0.02)
48	0.17 ( $\pm$ 0.05)	0.13 ( $\pm$ 0.08)

\*standard deviation

Residues at the injection site depleted slowly. However, using a conservative 30-hour half-life, residue at the injection site will deplete to a consumption adjusted tolerance of 1.0 ppm within 6 days. Muscle remote from the injection site was less than 0.075 ppm at 48 hours. A withdrawal period was calculated by a statistical procedure based on the kidney depletion data from this study. Using the 99% statistical tolerance limit with 95% confidence procedure on the residue depletion data for erythromycin in edible tissues, it was determined that a 6-day withdrawal period for cattle treated with up to 4 mg per pound body weight would be acceptable (less than 0.1 ppm erythromycin).

Temporary tissue irritation follows injection. To avoid excessive trim, cattle should not be slaughtered within 21 days of last injection.

Regulatory Method for Tissue Residues:

The regulatory analytical method for detection of residues of erythromycin is a microbiological test using Micrococcus luteus suspension. This method has been approved by the Food and Drug Administration and was fully validated by the research laboratory. The method is capable of measuring residues of erythromycin at the tolerance level of 0.1 part per million for edible tissues.

The supplemental application providing for the revision of the tolerance from "zero" to 0.1 ppm reflects the change in FDA policy regarding the concept of residue tolerance. No new toxicity data were used to revise the tolerance because 0.1 part per million is equivalent to the tolerance level that would have been established when the drug was originally approved (March 22, 1960). Furthermore, this tolerance is consistent with data supporting the published tolerance of 0.1 ppm in uncooked edible tissues of swine.

Under the zero tolerance concept, no detectable residues of a new animal drug were permissible in edible tissues of treated food animals when tissues were assayed using available analytical methods. However, as analytical technologies advanced, methodologies became increasingly sensitive and capable of measuring progressively smaller amounts of drug residues in tissues. Thus, residues which were not detectable using older, less sensitive methods (i.e., zero residues) began to be found using the more advanced analytical methods. Therefore, FDA adopted the concept of maximum negligible, or permissible, residues which reflect the lower level of quantitative sensitivity of the official regulatory analytical method. For erythromycin, this level is 0.1 part per million.

The validated regulatory analytical method for detection of erythromycin residues is filed in the Food Additives Analytical Manual on display in FDA's Freedom of Information Public Room (Room 12A-30), 5600 Fishers Lane, Rockville, MD 20857.

VII. AGENCY CONCLUSIONS:

The DESI finalization supplemental NADA satisfies the requirement of section 512 of the Act and demonstrates that GALLIMYCIN INJECTION, 200 mg/mL, when used in accordance with its proposed conditions of use, is safe and effective for the labeled indications. The approval provides for use of GALLIMYCIN INJECTION, 200 mg/mL for the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with Pasteurella multocida susceptible to erythromycin.

The "probably effective" finding of the NAS/NRC/DESI regarding Erythromycin which was published in the FEDERAL REGISTER of August 18, 1970 was subsequently reviewed by FDA, resulting in a January 21, 1976 letter to Sanofi. NADA 12-123 was upgraded to "effective" status with respect to the claim noted in the previous paragraph. The firm submitted revised labeling to conform to the letter and, therefore, this supplemental NADA complies with the NAS/NRC/DESI evaluation and FDA's conclusions.

GALLIMYCIN INJECTION, 200mg/mL for use in food-producing animals is currently on the market as an over-the-counter product. When the NADA was reviewed under NAS/NRC/DESI program, it was an over-the-counter product and this marketing status remains unchanged. Therefore, the Center for Veterinary Medicine has concluded that this product should retain over-the-counter marketing status.

Additionally, the supplemental application providing for revision of the tolerance from "zero" to 0.1 ppm for cattle is acceptable and is approved.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2) these are Category II changes. The approval of these changes are not expected to have any adverse effect on the safety of this new animal drug and, therefore, did not require a re-evaluation of the human food or target animal safety data in the parent application.

Under the Generic Animal Drug and Patent Term Restoration Act of 1988, these approvals do not qualify for an exclusivity period under section 512(c)(2)(F)(iii) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C.360b(c)(2)(F)(iii)) because the supplemental applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant.

# GALLIMYCIN®

Erythromycin Injection  
200 mg/mL

## DESCRIPTION:

GALLIMYCIN Injection is an erythromycin preparation formulated in a sterile solution for intramuscular administration only.

Each mL contains:

Erythromycin Base ... 200 mg

In a non-aqueous, buffered, alcohol base sterile solution.

## INDICATIONS AND USAGE:

GALLIMYCIN Injection is indicated for the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* organisms susceptible to erythromycin.

## WARNING:

Not for use in lactating dairy animals. Treated animals should not be slaughtered for food within 6 days of the last injection. Temporary tissue

irritation follows injection. To avoid excessive trim do not slaughter cattle within 21 days of the last injection.

## PRECAUTIONS:

In animals weighing over 200 lbs., the neck region is the preferred site for deep intramuscular injection. Since there may be a transient swelling or soreness at the site of injection, it is advisable, when more than one treatment is required, to vary the site of the injection. This is achieved by alternating sides of the neck or if necessary, alternating between the leg and neck muscles. No more than 10 mL should be injected at any one site (in small calves under 200 lbs. no more than 4 mL should be injected per site and then only in the heavy muscles of the leg). Swelling or soreness encountered at the site of injection is usually mild, transient and disappears in 2 to 4 days. Deep intramuscular injections will minimize the incidence of local soreness and swelling.

Restricted drug (CALIF.), use only as directed. Not for human use.

## DOSAGE AND ADMINISTRATION:

Deep intramuscular injection into the heavy neck muscles, or if necessary for alternating injection sites, into the heavy muscular portion of the leg muscle (round). In calves under 200 lbs., deep intramuscular injection into the heavy muscles of the leg only. Administer 2 mL/100 lbs. body weight (4 mg/lb. body weight) once daily for up to 5 days as needed. Use a 1-inch to 2-inch, 16- or 18-gauge needle depending on the animal's size.

Thoroughly clean and sterilize syringes and needles before using (needles and syringes may be sterilized by boiling in water for 15 minutes) or use prepackaged sterile syringes and needles.

Use all precautions to prevent contamination of contents of the bottle.

Disinfect the injection site

with a suitable disinfectant such as 70% isopropyl alcohol just prior to injection.

**STORAGE:**

Store at room temperature (15–30°C, 59–86°F).

**HOW SUPPLIED:**

Gallimycin is supplied in sterile 100 mL and 250 mL multiple-dose, rubber-stoppered vials. Available also in 500 mL multiple-dose, rubber stoppered vials for use with automatic multi-dose syringes.



**GALLIMYCIN<sup>®</sup>**

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**Erythromycin Injection  
200 mg/mL**



Manufactured for:  
Sanofi Animal Health, Inc.  
*a subsidiary of Elf Sanofi, Inc.*  
Overland Park, KS 66210  
GALLIMYCIN is a Reg. TM of ELF SANOFI

r4 file: 1 02.04.93 op: ls/mb area: mac1/Sanofi folder

code: SANO job: 6191 Sanofi KC Gallimycin 500 mL Sterile Solution label  
8" x 4"

(315) 472-3998



SCHUELER COMMUNICATIONS, inc.

r4 file: 1 02.04.93 op: ls/mb area: mac1/Sanofi folder

code: SANO job: 6191 Sanofi KC Gallimycin 500 mL Sterile Solution label  
8" x 4"

(315) 472-3998



SCHUELER COMMUNICATIONS, inc.

sanofi  
ANIMAL HEALTH

# GALLIMYCIN<sup>®</sup>

## Erythromycin Injection

### Sterile

### ANTIBACTERIAL FOR CATTLE

FOR ANIMAL USE ONLY

**NET CONTENTS:**  
500 mL sterile solution for use with  
automatic multi-dose syringes

**IMPORTANT:** See package insert for complete dosage information, directions, and precautions. Read entire package insert before using this product.

**INDICATIONS:** For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* organisms susceptible to erythromycin.

**Each mL contains:**  
Erythromycin Base ..... 200 mg  
in a non-aqueous, buffered, alcohol base.  
Restricted drug (CALIF.), use only as directed. Not for human use.

**DOSAGE:** For intramuscular injection only. Administer 2 mL/100 lbs of body weight (4 mg/lb) once daily for up to 5 days.

**STORAGE:** Store at room temperature (15–30°C, 59–86°F).

**WARNING:** Not for use in lactating dairy animals. Treated animals should not be slaughtered for food within 6 days of the last injection. Temporary tissue irritation follows injection. To avoid excessive trim do not slaughter cattle within 21 days of the last injection.



Manufactured for:  
Sanofi Animal Health, Inc.  
a subsidiary of *Elf Sanofi, Inc.*  
Overland Park, KS 66210

GALLIMYCIN is a Reg. TM of ELF SANOFI.

Mfd. in USA

Lot No.:  
Exp. Date:

r4 file: 1 02.03.93 op: ls/mb/ls-mb area: mac1/Sanofi folder

code: SANO job: 6190 Sanofi KC Gallimycin 250 mL Sterile Solution label  
8" x 3"

(315) 472-3998



SCHUELER COMMUNICATIONS, inc.

r4 file: 1 02.03.93 op: ls/mb/ls-mb area: mac1/Sanofi folder

code: SANO job: 6190 Sanofi KC Gallimycin 250 mL Sterile Solution label  
8" x 3"

(315) 472-3998



SCHUELER COMMUNICATIONS, inc.

sanofi  
ANIMAL HEALTH

# GALLIMYCIN<sup>®</sup>

## Erythromycin Injection

### Sterile

ANTIBACTERIAL  
FOR CATTLE

FOR ANIMAL USE ONLY

**NET CONTENTS:** 250 mL sterile solution

**IMPORTANT:** See package insert for complete dosage information, directions, and precautions. Read entire package insert before using this product.

**INDICATIONS:** For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* organisms susceptible to erythromycin.

**Each mL contains:**  
Erythromycin Base ..... 200 mg  
In a non-aqueous, buffered, alcohol base.  
Restricted drug (CALIF.), use only as directed. Not for human use.

**DOSAGE:** For intramuscular injection only. Administer 2 mL/100 lbs of body weight (4 mg/lb) once daily for up to 5 days.

**STORAGE:** Store at room temperature (15–30°C, 59–86°F).

**WARNING:** Not for use in lactating dairy animals. Treated animals should not be slaughtered for food within 6 days of the last injection. Temporary tissue irritation follows injection. To avoid excessive trim do not slaughter cattle within 21 days of the last injection.



Manufactured for:  
Sanofi Animal Health, Inc.  
a subsidiary of Elf Sanofi, Inc.  
Overland Park, KS 66210

GALLIMYCIN is a Reg. TM of ELF SANOFI.

Mfd. in USA

Lot No.:  
Exp. Date:

May 22, 2007

Each mL contains:  
Erythromycin base .....100 mg  
in a non-aqueous, buffered, alcohol base.

**IMPORTANT:** See package insert for complete dosage information, directions, and precautions. Read entire package insert before using this product.

**PROTECT FROM FREEZING**  
**STORE AT ROOM TEMPERATURE, 15-30°C (59-86°F)**

TAKE TIME  **OBSERVE LABEL DIRECTIONS**

Manufactured by: Bimeda-MTC Animal Health Inc.  
Cambridge, ON N3C 2M4  
Bimeda, Inc. and Bimeda-MTC Animal Health Inc.  
are Divisions of Cross Vetpharm Group Ltd.

UPC CODE  
8 99855 60009 7

**Gallimycin®-100**  
Erythromycin Injection  
100 mg per mL

**Antibacterial for Cattle**

For Intramuscular Injection Sterile

**FOR ANIMAL USE ONLY**  
**KEEP OUT OF REACH OF CHILDREN**

Net Contents:  
100 mL (3.4 FL OZ)



**INDICATIONS:** For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* organisms susceptible to erythromycin.

**DOSEAGE:** For intramuscular injection only. Administer 4 mL/100 lbs of body weight (4 mg/lb) once daily for up to 5 days.

**WARNING:** Treated animals should not be slaughtered for food within 6 days of the last injection. Temporary tissue irritation follows injection. To avoid excessive trim do not slaughter cattle within 21 days of the last injection. Do not use in female dairy cattle greater than 20 months of age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Manufactured by: Bimeda, Inc. La Sane, MN 56258  
Gallimycin is a Registered Trademark of Bimeda, Inc.  
Patent No. 4,649,841 464,984 Rev. 05/07

Base 1.875" X 6"  
Leaflet 1.875" X 10.125"

if necessary for alternating injection sites, into the heavy muscular portion of the leg muscle (round). In calves under 200 lbs., deep intramuscular injection into the heavy muscles of the leg only. Administer 4 mL/100 lbs. body weight (4 mg/lb body weight) once daily for up to 5 days as needed. Use a 1-inch to 2-inch, 16 or 18 gauge needle depending on the animal's size.

**STORAGE:**  
STORE AT ROOM  
TEMPERATURE, 15-30°C  
(59-86°F).

**HOW SUPPLIED:**  
Gallimycin is supplied in sterile 100 mL multiple-dose, rubber-stoppered vials.

**Restricted Drug (California);**  
Use only as directed.

**FOR ANIMAL USE ONLY**  
**KEEP OUT OF REACH OF**  
**CHILDREN**

TAKE TIME  **OBSERVE LABEL**  
**DIRECTIONS**

Manufactured by:  
Bimeda-MTC Animal Health Inc.  
Cambridge, ON N3C 2M4

Manufactured by:  
Bimeda, Inc. La Sane, MN 56258

Bimeda, Inc. and Bimeda-MTC Animal Health Inc.  
are Divisions of Cross Vetpharm Group Ltd.

**INDICATIONS:** For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* organisms susceptible to erythromycin.

**DOSEAGE:** For intramuscular injection only. Administer 4 mL/100 lbs of body weight (4 mg/lb) once daily for up to 5 days.

**WARNING:** Treated animals should not be slaughtered for food within 6 days of the last injection. Temporary tissue irritation follows injection. To avoid excessive trim do not slaughter cattle within 21 days of the last injection. Do not use in female dairy cattle greater than 20 months of age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Manufactured by: Bimeda, Inc. La Sane, MN 56258  
Gallimycin is a Registered Trademark of Bimeda, Inc.  
Patent No. 4,649,841 464,984 Rev. 05/07

Pull

**Gallimycin®-100**  
Erythromycin Injection  
100 mg per mL

**DESCRIPTION:**  
Gallimycin®-100 Injection is an erythromycin preparation formulated in a sterile solution for intramuscular administration only.

**Each mL contains:**  
Erythromycin base .....100 mg  
in a non-aqueous, buffered,  
alcohol base sterile solution.

**INDICATIONS AND USAGE:**  
Gallimycin®-100 Injection is indicated for the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* organisms susceptible to erythromycin.

**WARNING:**  
Treated animals should not be slaughtered for food within 6 days of the last injection. Temporary tissue irritation follows injection. To avoid excessive trim do not slaughter cattle within 21 days of the last injection. Do not use in female dairy cattle greater than 20 months of age. A withdrawal period has not

been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**PRECAUTIONS:**  
In animals weighing over 200 lbs., the neck region is the preferred site for deep intramuscular injection. Since there may be transient swelling or soreness at the

site of injection, it is advisable, when more than one treatment is required, to vary the site of the injection. This is achieved by alternating sides of the neck if necessary, alternating between the leg and the neck muscles. No more than 10 mL should be injected at any one site (in small calves under 200 lbs. no more than 4 mL should be injected per site and then only in the heavy muscles of the leg).

Swelling or soreness encountered at the site of the injection is usually mild, transient and disappears in 2 to 4 days. Deep intramuscular injections will minimize the incidence of local soreness and swelling.

**DOSEAGE AND ADMINISTRATION:**  
Deep intramuscular injection into the heavy neck muscles, or