TULIEVE[®] (tulathromycin injection)

Tulieve[®] (tulathromycin injection) is the affordable alternative to Draxxin® (tulathromycin injection) Injectable Solution. It delivers the same single-shot, rapidly absorbed, long acting, broad-spectrum activity against an equally wide range of diseases, and thanks to our exclusive plastic bottles, has less risk of product loss.

- Ready-to-use semi-synthetic macrolide antibiotic
- Low-volume dose
- Single shot, rapidly absorbed and long acting
- Highly effective, broad-spectrum antibiotic
- Available in 1 Liter and 500 mL plastic hanger bottles
- Also available in 250 mL and 100 mL plastic bottles
- Plastic bottles reduce risk of product loss
- Short meat withdrawal times 18 days beef, 5 days swine
- FDA approved

Non-Lac Calves),	For Beef Cattle (Including Suckling Calves), Non-Lactating Dairy Cattle (Including Dairy Calves), and Veal Calves .* Not for use in female dairy cattle 20 months of age or older.				
Disease	Bacteria				
Treatment of Bovine Res Disease (BRD) associat					
Control of respiratory dis cattle at high risk of deve BRD associated with	Pasteurella multocida				
Treatment of infectious b keratoconjunctivitis (IBK (Pinkeye) associated wit) Moraxella bovis				
Treatment of bovine Foo (interdigital necrobacillo associated with	i decodacionam				

*for calves: only the BRD treatment label applies

IMPORTANT SAFETY INFORMATION FOR CATTLE: Do not use in female dairy cattle 20 months of age or older, including dry dairy cows. A pre-slaughter withdrawal time has not been determined
for pre-ruminating calves. Effects on reproductive performance, pregnancy, and lactation have not been determined. Tulieve has a pre-slaughter withdrawal time of 18 days. Tulieve should not be
used in animals known to be hypersensitive to the product.

IMPORTANT SAFETY INFORMATION FOR SWINE: Tulieve has a pre-slaughter withdrawal time of 5 days. Tulieve should not be used in animals known to be hypersensitive to the product.

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Disease	Bacteria
Treatment of Swine Respiratory Disease (SRD) associated with	Actinobacillus pleuropneumoniae Pasteurella multocida Bordetella bronchiseptica Haemophilus parasuis Mycoplasma hyopneumoniae
Control of SRD, in groups of pigs where SRD has been diagnosed, associated with	Actinobacillus pleuropneumoniae Pasteurella multocida Mycoplasma hyopneumoniae



Scan this QR code to see our Tulieve video. For more information, contact your veterinarian, animal health provider or visit Norbrook.com.

Tulieve 🕅

(tulathromycin injection)

Injectable Solution

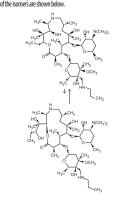
Antibiotic

100 mg of tulathromycin/mL

For use in beef cattle (including suckling calves), non-lactating dairy cattle (including dairy calves), veal calves, and swine. Not for use in female dairy cattle 20 months of age or older. CAUTION: Federal (USA) law restricts this drug use by or on the order of a licensed veterinarian

Clicit North Texted (University and Construction and Construction) DESCRIPTION: Tultivee" injectable Solution is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antibiotic of the subclass triamilide. Each mul of Tulere contains 100 mg of tulathromycin, S00 mg propylene glycol, 192 mg oftic add and S mg monothioglycerol. Sodium hydroxide or hydrochloric add mg/be added to adjust pH. Tulere consists of an equilibrated mixture of two isomeric forms of tulathromycin in a 9:1 ratio. Structures of the isomers are shown below.

Figure 1.



The chemical names of the isomers are (2R,3S,4R,5R,8R,10R,11R,125,13S,14R)-13-[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C ([oropylamino])methyl[-0-c-thich-hexopyrano-sylloxy]-2 ethyl-3,410-thitydowz,35,810,12 (Hackmaenthyl-11-[3,64 thicdowz)-3 (imethylamino)-P-ydv-hexopyranosylloxy]-1-wa-6-zazydopertadecan-15-one and (2R,3R,6R,8R,9R,10S,11S,12R)-11-[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C ((iropylamino)methyl-1-tho-hexopyrano-sylloxy]-1-((iR,2R)-1,2-diducoy-1--methyl-1-0-methyl-4-tho-hexopyrano-sylloxy]-1-((iR,2R)-1,2-diducoy-1-methyl-1-0-methyl-4-tho-hexopyrano-sylloxy]-1((iR,2R)-1,2-diducoy-1-methyl-1-0-methyl-4-tho-hexopyrano-sylloxy]-1((iR,2R)-1,2-diducoy-1-methyl-1-0-methyl-4-thickoy-1-methyl-1-0-methyl-3), (interval-sylloxy]-1-(interval-sylloxy]-1-(interval-sylloxy]-1-(interval-sylloxy]-1-(interval-sylloxy]-1-(interval-syllox)-1-(in

INDICATIONS

Indicional Beef and Non-Lactating Dairy Cattle BRD -Tulkive Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with Mancherinio hearowycine, Posteurella multocida, Histophilus sormi, and Mycoplasma bovis, and for the control of respiratory disease in cattle at high risk of developing BRD associated with Mannherinia hearowycine, Posteurella multocida, Histophilus sormi, and Mycoplasma bovis. IBK-Tulice Injectable Solutions indicated for the treatment of infectious bovine keratoconjunctivitis (BK) zooraintd with Menarella boxit.

IBM-luive injectable Solution is indicated for the treatment of mitectious powne keratoconjunctivius (BK) associated with *Moreallo lowis*. Foot Rot-Tulieve Injectable Solution is indicated for the treatment of bovine foot rot (interdigital neorbaalicus) associated with *Husbacharium neorphonum* and *Paphyromanas levii*. Suckling Calves, Dairy Calves, and Veal Calves BRD-Tulieve Injectable Solution is indicated for the treatment of BRD associated with *M. haemolytica*, *Pranulscial*, H. Somi, and M. Jovs.

Swine Utileve Injectable Solution is indicated for the treatment of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Posteurella muthocida, Boardetella branchiseptica, Haemophilus paraxis, and Myoeplasma hyopeneumoniae; and for the control of SRD associated with Actinobacillus pleuropneumoniae. Posteurella multocida, and Mycaplasma hyopneumoniae in groups of pigs where SDI has been diagnosed. DOSAGE AND ADMINISTRATION

Cattle

Inject subcutaneously as a single dose in the neck at a dosage of 2.5 mg/kg (1.1 mL/100 lb) bodyweight (BW). Do not inject more than 10 mL per injection site.

Table 1. Tulieve Cattle Dosing Guide

Animal Weight (Pounds)	Dose Volume (mL)
100	1.1
200	2.3
300	3.4
400	4.5
500	5.7
600	6.8
700	8.0
800	9.1
900	10.2
1000	11.4

Inject intramuscularly as a single dose in the neck at a dosage of 2.5 mg/kg (0.25 mL/22 lb) BW. Do not inject more than 2.5 mL per injection site. Table 7 Tuliava Swine Docing Guida

able 2. Tulleve Swille Dosilig Guiu	e
Animal Weight (Pounds)	Dose Volume (mL)
15	0.2
30	0.3
50	0.6
70	0.8
90	1.0
110	1.3
130	1.5
150	1.7
170	1.9
190	2.2
210	2.4
230	2.6
250	2.8
270	3.1
290	33

CONTRAINDICATIONS

The use of Titleve Injectable Solution is contraindicated in animals previously found to be hypersensitive to the drug.

WARNINGS FOR USE IN ANIMALS ONLY. NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN. NOT FOR USE IN CHICKENS OR TURKEYS.

RESIDUE WARNINGS Cattle

Carbie (arbie intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves bom to these cows. Swine

Swine intended for human consumption must not be slaughtered within 5 days from the last treatment

PERCINITIONS Cattle The effects of fulathromycin injection on bovine reproductive performance, pregnancy, and lactation have not been determined. Subcutaneous injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

The effects of tulathromycin injection on porcine reproductive performance, pregnancy, and lactation have not been determined. Inframuscular injection can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

ADVERSE REACTIONS Cattle

Cattle In one BRD field study, two calves treated with tulathromycin injection at 2.5 mg/kg BW exhibited transient hypersalivation. One of these calves also exhibited transient dyspnea, which may have be related to pneumonia.

related to fineumonia. Swine In one field study, one out of 40 gips freated with tulathromycin injection at 2.5 mg/lg BW exhibited mild salvation that recover in less than four hours. POGT APPROVAL LEPREINCE The following adverse events are based on post approval adverse drug experience reporting. Not all adverse events are reported to the FDA CVM. It is not advays possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events are reported to the FDA conduct exposure using these data. The following adverse events are listed in decreasing order of reporting frequency in article injection site reactions and anaphylasis/anaphylasticati reactions. For a complete listing of adverse reactions for tulathromycin injection reported to the CVM see: www.fda.gov/reportanimalae.

CLINICAL PHARMACOLOGY

CLINICAL PHARMACOLOGY At physiological by fulathromyoin (a weak base) is approximately 50 times more soluble in hydrophilic than hydrophobic media. This solubility profile is consistent with the extracellular pathogen activity typically associated with the macrolides.¹ Marked/h higher tulathromyoin concentrations are observed in the lungs as compared to the plasma. The extent to with hung concentrations prevent the (active) drug was not examined. Therefore, the dinical relevance of these elevated lung concentrations is underturniced.

undetermined. Although the relationship between tulathromycin and the characteristics of its antimicrobial effects has Although the relationship between tulathomycin and the characteristic of its antimicrobial effects has not been characterisd, as dats, macrolides tend to be primarily bacterioistatic, but may be bacterioidal against some pathogens.² They also tend to exhibit concentration independent killing, the rate of bacterial readiation to explore the major characteristic series and the minimum initiatory concentration. MG of the targetied pathogen. Under these conditions, the time that serum concentrations remain above the MIC becomes the major determinant of antimicrobial activity. Macrolides also explore the MIC becomes the major determinant of antimicrobial activity. Macrolides also explore the MIC becomes the macrolide concentration and the exposure time, the pathogen dependent. In general, by increasing the macrolide concentration and the exposure time, the def will increase to some maximal duration. Of the torwardse, concentration and becomes time, drug concentration tends to be the most powerful determinant of the duration of PAIL. Liathtromycin is beinimated from the body primarily uncharged via bilage vecretion. "Carbon, C. 1998. Pharmacodynamics of Nacrolides, Atalides, and Streptogramins: Effect on Extracellular Pathogens. Clin. Infect, Da, 728-32. "Nightingale, CL. 1997. Pharmacokinetics and Pharmacodynamics of Nacrolides. Pediatr. Infect. bis. **1**, **1**, **6**, **4**, **4**, **3**.

Dis. J., 16:438-443. Cattle Following subcutaneous administration into the neck of feeder calves at a dosage of

Cattle following subcutaneous administration into the neck of feeder calves at a dosage of 2.5 mg/kg BW, tuathormycin is apily and nearly completely absorded. Peok plasma concentrations generally occur within 15 minutes after dosing and product relative bioavailability exceeds 90%. Total systemic clearance is approximately 170 mL/trika, Tulathormycin distributes extensively into body tissues, as evidenced by volume of distribution values of approximately 111 (Tug in healthy runniating calves.³ This extensive volume of distribution site argo proprioritately 111 (Tug in healthy runniating calves.³ This extensive volume of distribution site argo proprioritately 112 (Tug in healthy runniating calves.⁴ This extensive volume of distribution is algoed on quantifiable terminal plasma drug concentrations) versus 8.75 days for total lung concentrations (based on quantifiable terminal plasma drug concentrations) versus 8.75 days for total lung concentrations (based on data from healthy animals). Linear pharmacokinetic differences are observed in castated male versus female calves. ⁴ Clearance and volume estimates are based on intersubject comparisons of 2.5 mg/kg BW obs 00 within subcutaneous or intravenous intercions.

¹ Gearance and volume estimates are based on intersubject comparisons of 2.5 mg/kg BW administered by either subcatances or intracenous injection. Swine Following intramuscular administration to feeder pigs at a dosage of 2.5 mg/kg BW, tulathromycin is completely and rapidly absorbed ($T_{\rm int} - 0.25$ hour). Subsequently, the drug rapidly distributes into body issues, achieving a volume of distribution exceeding 15 Lkg. The free drug is rapidly deared from the systemic dirallation ($T_{\rm int} - 0.25$ hour). Subsequently, the drug rapidly distributes into body issues, achieving a volume of distribution exceeding 15 Lkg. The free drug is rapidly deared from the systemic dirallation ($T_{\rm interminal elimination half-Hife (60 Do bours) owing to its certainsive oblume of distribution. Although pulmonary tulathromycin concentrations are substantially higher than concentrations observed in the plasma, the chincil significance of these findings is undetermined. There are no gender differences in swine tulathromycin pharmacokinetics.$

MICROBIOLOGY

Microbiology Cattle Fuldstromycin has demonstrated in vitro activity against Mannheimia hoemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis, four pathogens associated with BRD; against Moravella bovis associated with IBK; and against Fusobacterium neorophorum and Porphyromonas levii and the source data with the source of the s

Moracella boxis associated with IBK3 and against *Fusobacterium necorphorum* and *Paphyromionas levi* associated with boxine foot not. The MICs of tulathromycin against indicated BBD and IBK pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLS), M31-A2). The MICs against floot to pathogens were also determined tors Biostore commended by the CLS (M11-A6). All MIC values were determined using methods: Bioslates obtained from calves enrolled in therapeutic and at-risk field studies in the U.S. in 1999. In the therapeutic studies, isolates were obtained from pertentment asspharyngeal was born all study calves, and from lung swabs or lung tissue of saline-treated calves that clied. In the at-risk studies, solates were obtained from resorbarnoreal claubs of saline at-reated enon-zenorodies and from lung swabs or lung tissue of saline-treated calves that clied. In the at-risk studies, solates were obtained from resorbarnoreal claubs for single at-reader enon-zenorodies and from lung swabs or

lung tissue of saime-treated calves that deel. In the at-risk studies, solates were obtained from nasopharyngeal shakes of saime-treated non-responders, and from lung svaks or lung tissue of saline-treated calves that died. The results are shown in Table 3. **IBK** - The MICs of tulathromytin were determined for *Monaella bovis* isolates obtained from calves enrolled in IBK first divuties in the ULS in 2004. Kolates were obtained from pre-treatment conjunctival svaks of calves with china classing of IBK enrolled in the tulathromycin injection and saline-treated constructions.

Swab to clave with clinical signs on low entoneen in the traductority in nijectural and same-treated groups. The results are shown in Table 8. Foot Rot-The NICs of tulationowycin were determined for *Flusobactesium neorophorum* and *Porphyromonas levirobtained* from restemant interdigital biopsies and swabs of cattle with clinical signs of foot tot enrolled in the tulathromycin injection and saline-treated groups. The results are shown in Table 3.

Table 3. Tulathromycin minimum inhibitory concentration (MIC) values* for indicated pathogens isolated from field studies evaluating BRD and IBK in the U.S. and from foot rot field studies in the U.S. and Canada

Indicated pathogen	Date Isolated	No. of isolates	МІС ₅₀ ** (µg/mL)	MIC,,** (µg/mL)	MIC range (µg/mL)
Mannheimia haemolytica	1999	642	2	2	0.5 to 64
Pasteurella multocida	1999	221	0.5	1	0.25 to 64
Histophilus somni	1999	36	4	4	1 to 4
Mycoplasma bovis	1999	43	0.125	1	≤0.063 to >64
Moraxella bovis	2004	55	0.5	0.5	0.25 to 1
Fusobacterium necrophorum	2007	116	2	64	≤ 0.25 to >128
Porphyromonas levii	2007	103	8	128	≤ 0.25 to >128

*The correlation between in vitro susceptibility data and clinical effectiveness is unknown. **The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

⁴The towers ML to excompass 3VP and 9VPs of the most supergible solates, respectively, Swine In vitro activity of tulathromycin has been demonstrated against Actinobacillus pleuropneumonice. The MLG of tulathromycin against indicated SRD pathogens were determined using methods recommended by the Clinical and Ladorabory Standards Institute (CLS), MSI-4 and MSI-43). MIGs for *Hearnophilus parasuis* were determined using Veterinary Fastidious Medium and were incubated up to 48 hours at 35 and 57 Cin a QL - emotioned atmosphere. All MIC values were determined using the 9:1 isomer ratio of this compound. Isolates obtained in 2000 and 2002 were from lung samples from saline-treated pigs and non-treated sentinel pigs enrolled in Treatment of SRD field studies in the U.S. and Canada. Boldes obtained in 2007 and 2008 were from lung samples from saline-treated pigs and non-treated pigs enrolled in the Control of SRD field study in the US. and Canada. The results are shown in Table 4. The results are shown in Table 4

Table 4. Tulathromycin minimum inhibitory concentration (MIC) values* for indicated pathogens isolated from field studies evaluating SRD in the U.S. and Canada.

Indicated pathogen	Date Isolated	No. of isolates	MIC_** (µg/mL)	MIC _{,0} ** (µg/mL)	MIC range (µg/mL)
Actinobacillus pleuropneumoniae	2000-2002 2007-2008	135 88	16 16	32 16	16 to 32 4 to 32
Haemophilus parasuis	2000-2002	31	1	2	0.25 to >64
Pasteurella multocida	2000-2002 2007-2008	55 40	1	2	0.5 to >64 ≤0.03 to 2
Bordetella bronchiseptica	2000-2002	42	4	8	2 to 8

The correlation between in vitro susceptibility data and clinical effectiveness is unknown. ** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

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**The buset MC the examples SWard 9% of the most succeptible isolates, respectively.
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BRD-In a multi-location field study, 31 4 cakes with naturally occurring BRD were treated with the
ultahtnorymin injection. Responses to treatment were compared to saline-treated cakes of 510PF on
by 41. The current were significantly higher (P > 0.00) in lutahtnorymin injection-treated cakes (74%).
Compared to saline treated cakes (74%). There were two BRD-elated deaths in the tulathnorymin injection-treated cakes (74%).
Compared to saline treated cakes (74%). There were two BRD-elated deaths in the sultahtnorymin injection-treated cakes (74%).
Compared to saline treated cakes (74%).
There were two BRD-elated deaths in the saline-treated cakes.
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Compared to saline treated cakes and 27 saline-treated cakes (74%).
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There were use topolicited and 28% of 71/12% (71/2%) (71/2%) (71/2%).
Compared to saline treated cakes (74%).
Compared to saline treated cakes (74%).
There were cateporized to compare the BRD treatment failures.
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Collexe were cateporized to the tapopulo of fultationnymin injection in the ULL and nine
componenous studies conducted for the approval of fultationnymin injection in the BRD treatment early in advance and the saline-treated cakes.
Collexee were conducted to frame the BRD treatment success rate in fourge daves.
Collex

calve: compared with salme treated calves (60% vs. 3%, P < 0.000 nn 83.3% vs. 50%, P = 0.0088). **Swine** In a multi-location field study to evaluate the treatment of naturally occurring SP0, 266 pigs were texted with tulathromycin injection. Response to treatment were compared to salme treated controls. Success was defined as a pig with normal atitude, normal respiration, and rectal temperature of < 104° F on Day (70.5%) compared to salme-treated pigs (46.1%). The treatment were vanisolated from flocks line thread and non-treated sentine Jps: in this study. Two induced infection model studies were conducted to confirm the effectiveness of fuldimorp(in life) study. The programmical is that and the same study is the same study with a field stan of M. Ingomerunnoize. If Hags were included with either tulathromycin injection 12 surges BW) intranuscularly or an equivalent volume of saline. Prog were evaluated and non-treated pigs in this study. Two induced infection model studies were conducted to confirm the effectiveness of fuldimorp(in life) study. The mean precentage of cross pneumonic line (sins) was astistically significantly lower (P < 0.0001) for tulathromycin injection 12 meated pigs than for saline- threated pigs in both studies (S2N vs. 23.62 and 13.1% vs. 26.42%). The effectiveness of fuldimomycin injection (26 pigs) or saline (22) pigs, Responses to studies and the advective of the act 15% of the study condicates stowed clinical signs of S10, all pigs were enrolled and treated with tulathromycin injection (25 pigs) or saline (22) pigs, Responses to treatment were enalized to pigs. 70.24%), compared to saline-treated pigs in fully or saline science (P < 0.005) in tulathromycin injection -treated pigs compared to saline-treated pigs (59.2% vs. 41.2%). **ANIMAL SAFETY**

ANIMAL SAFETY

Cattle

Cattle Safety studies were conducted in feeder calves receiving a single subcutaneous dose of 25 mg/kg BW, or 3 weekly subcutaneous doses of 2.5, 7.5, or 1.2.5 mg/kg BW. In all groups, transient indicators of pain after injection were seen, including head shaking and pawing at the ground, injection site swelling, discloration of the subcutaneous tissues at the injection site and corresponding histopathologic changes were seen in animals in all dosage groups. These issions showed signs of resolving over time. No other drug-related lealow were observed macroscopically or microscopically. An exploratory study was conducted in feeder calves reteiving a single subcutaneous dose of 10, 1.2.5, or 15 mg/kg BW. Macroscipial, no leasons were observed. Microscopically, mismal on main dimonarial degeneration was seen in one of six calves administered 125 mg/kg BW and two of six calves administered 15 mg/kg BW. A safety study was conducted in per unmana Lokes 13 ho 27 days of a ge receiving 2.5 mg/kg BW one subcutaneous buctaneously. With the exception or finnimal to mild neigection site reactions, no drug-related clinical signs or other lessons were observed Microscopically or microscopically.

Swine Safety studies were conducted in pigs receiving a single intramuscular dose of 25 mg/kg BW, or 3 weekly intramuscular doses of 2.5, 7, 5, or 12.5 mg/kg BW. In all groups, transient indications of pain after injection were seen, including restlessness and excessive vocalization. Themos occurred briefly in one animal receiving 75 mg/kg BW. Discoloration and efferma of injection site tissues and corresponding histopathologic changes were seen in animals at all dosages and resolved over time. No other drug-related lesions were observed macroscopically or microscopically.

STORAGE CONDITIONS

STORAGE CONDITIONS Store 35° to 65° f15° to 30°C). Exposure to temperature up to 104°F (40°C) may be tolerated provided the mean kinetic temperature does not exceed 77°F (25°C); however, such exposure bondle berninimized. Exposure to temperature down to 36°C/C2 (may be tolerated. For 50 & 100 mL viais: Use within 60 days of the first puncture and puncture a maximum of 52 times. For 250, 500 & 1000 mL viais: Use within 60 days of the first puncture and puncture a maximum of 80 times. If vising a needle or draw-off spike larger than 16 gauge discard any remaining product immediately after use. HOW SUPPLIED

Tulieve Injectable Solution is available in the following package sizes: 50 mL vial, 100 mL vial, 250 mL vial, 500 mL vial, 1000 mL vial

Approved by FDA under ANADA # 200-723

Tulieve® is a registered trademark of Norbrook Laboratories Limited Made in the UK

Manufactured by

Norbrook Laboratories Limited, Newry, BT35 6PU, Co. Down, Northern Ireland

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (DS), contact Norbrook at 1-866-591-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/repor-tanimalae.

Revised Feb 2022



