# Banamine® Transdermal Technical Bulletin

## Dosing Site and Leather Quality Assessment Following Administration of Flunixin Transdermal Solution

### Background

In veterinary medicine, transdermal formulations are developed for several reasons: to facilitate administration, decrease animal stress, reduce the need for full-restraint handling and to reduce the number of injections sites to support beef quality assurance initiatives. Because these formulations are dosed onto the back of animals, specific attention is paid to topical safety, reactivity and any effect it may have on hide quality. According to U.S. Census Bureau trade data, the value of U.S. hide, skin and leather exports totaled $2B in 2016.[1]

A new Banamine® Transdermal (flunixin transdermal solution) has been developed as a pour-on product to be applied along the dorsal midline in cattle. Several studies were conducted to observe and quantify any skin surface reactions, including:

1. Post-treatment Dosing Site Assessment Following Topical Administration of a Novel Formulation of Flunixin Transdermal Solution: Summary of Seven Studies[2]

2. Effect of Flunixin on Leather Quality of Cattle Treated with a Banamine Transdermal Solution[3]

This bulletin reports all of these data.

### STUDY 1

### Objective

To evaluate hide response post administration of Banamine Transdermal in multiple body weight ranges, geographic locations and beef cattle breeds in the United States.

### Materials and Methods

Seven prospective, randomized, masked studies were conducted in three locations in the United States (Figure 1). Treatments were administered in January, March, August and October in warm and cold environments.

Animals included in the studies were bulls, steers, cows and heifers with body weights ranging from 319 to 1,541 pounds. Cattle breeds included purebred and crossbred Angus, Charolais, Hereford, Holstein, Wagyu and Bos indicus cross (between 3/8 and 7/8 Bos indicus in their bloodline).

- 632 animals each received a single dose of Banamine Transdermal at either 2.5 or 5.0 mg/kg (the label dose is 3.33 mg/kg)
    - o 301 and 331 animals were given 2.5 and 5.0 mg/kg, respectively
- 141 animals served as the negative control animals

Banamine Transdermal was given on Day 0 in all studies. Each animal was restrained and individually examined at multiple times after dosing – ranging from Day 2 to Day 42 after dosing.

### Results

Environmental temperatures on the day of dosing ranged from 16˚F to 95˚F. Results of the studies indicated that Banamine Transdermal was well tolerated in most animals. Examination of the animals indicated that most of the animals dosed with Banamine Transdermal at 2.5 or 5.0 mg/kg had no or only mild reactions at any time. Common observations included skin flaking, dandruff, broken/brittle hair, thickened skin without signs of inflammation, and alopecia (thinning or bald spots). These also were observed in untreated control animals though to a lesser extent.

The skin reactions observed on Banamine Transdermal-treated and untreated control animals were considered acceptable for normal cattle-handling practices.

The number of treated animals exhibiting mild reactions increased over time after dosing, peaking between Days 10 and 28. Dosing site reactions were transient and resolved within six to seven weeks after dosing.

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## Conclusions

These studies indicated that Banamine Transdermal was well tolerated on the skin in a wide range of cattle breeds and a broad range of ambient temperatures. Transient skin reactions – consisting of skin flaking, dandruff, broken/brittle hair, and thickened skin without signs of inflammation – resolved without treatment and were acceptable for normal cattle-handling conditions.

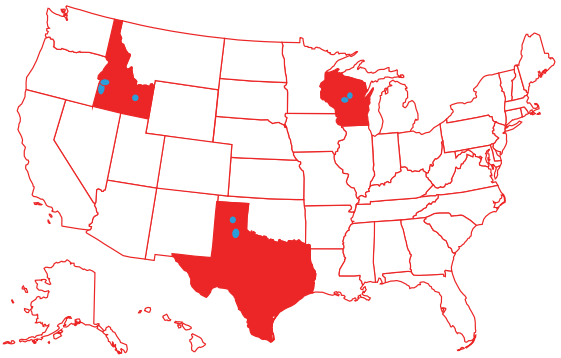

**Figure 1.** Location sites of seven studies to evaluate hide response following administration of Banamine Transdermal formulation (Idaho [3], Texas [2] and Wisconsin [2])

## STUDY 2

### Objective

To evaluate any association to defects in leather quality from cattle previously treated with Banamine Transdermal compared to placebo-treated, negative controls.

### Materials and Methods

Twenty cattle between 16 and 22 months old were treated once with Banamine Transdermal (3.3 mg/kg BW, eq. 1.0 mL/15 kg BW) and 10 animals served as the placebo (NaCl 0.9 percent with red dye). Treatment and placebo were poured as a line on the dorsum along the backbone. Cattle were slaughtered at two or eight weeks post treatment (10 treated and five placebo cattle per time point).

Complete raw hides were recovered from the carcasses and processed into semi-finished leather quality, using standard tannery procedures. Based on leather thickness, ISO specifications for safety shoes, clothing and/or upholstery manufacturing were used for samples collected from the standard area (SA) and from the dosing site backline area (BLA) (Figure 2).

### Results

#### In Vivo Local Tolerance

Dandruff, without any local reaction or irritation of the skin, was observed for all treated and untreated cattle within the first six days after treatment.

#### Physio-mechanical Characteristics

All SA and BLA leather samples, tear strength and grain distention were within the specified tolerance ranges (Table 1).

For SA samples, 20 percent of control leathers and 5 percent of treated leathers were out of the 40-80 percent quality range for elongation at break; 5 percent of treated leathers and no control hides were below the threshold value of 1.2 daN/mm$^2$ for tensile strength. According to the ISO 20345 standard for safety shoes, the threshold value for tensile strength is 1.2 daN/mm$^2$.

For BLA samples, 70 percent of control leathers and 25 percent of treated leathers were out of the quality range for elongation at break; 50 percent of control leathers and 25 percent of treated leathers were below the standard for tensile strength (Table 1).

### Conclusions

Banamine Transdermal did not induce visual local reaction, irritation, swelling or thickening of the skin nor alter its structure. Also, based on results obtained for physio-mechanical characteristics of samples collected on the standard area and on the dosing site area, leather from cattle treated with Banamine Transdermal was not considered to be lower quality than placebo treated skins.

No test-article-related effects were observed on raw hide and leather appearance. Although a couple of treated hides had a value from the standardized areas that was outside the specified ranges, the placebo-treated hides also had out-of-range results. The leather from both treatment groups would have been considered

as suitable for safety shoes, clothing or upholstery manufacturing.

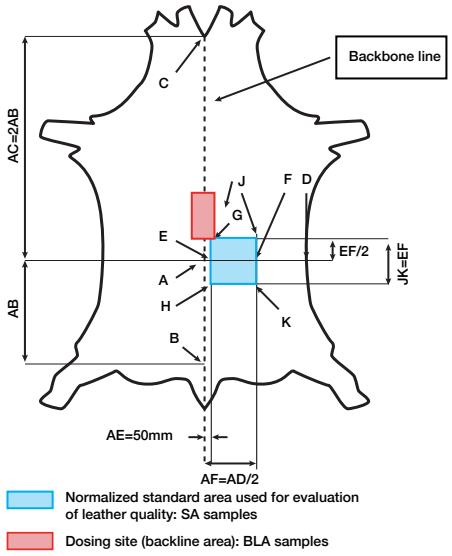


**Figure 2.** Hide sample locations of the SA and of the dosing site BLA from cattle slaughtered at two or eight weeks after application of Banamine Transdermal

**STANDARDIZED AREA (SA)**

| Treatment Group | Time post dosing (week) | Tensile Strength[a] | Elongation at break[a] | Tear strength[b] | Grain distention[c] |
|---|---|---|---|---|---|
| Control | 8 | 0 | 2 | 0 | 0 |
| | 2 | 0 | 0 | 0 | 0 |
| Out of range | | 0/5 (0%) | 2/10 (20%) | 0/10 (0%) | 0/10 (0%) |
| Treated | 8 | 0 | 0 | 0 | 0 |
| | 2 | 1 | 1 | 0 | 0 |
| Out of range | | 1/20 (5%) | 1/20 (5%) | 0/20 (0%) | 0/20 (0%) |

**DOSING SITE AREA (BLA)**

| | | | | | |
|---|---|---|---|---|---|
| Control | 8 | 2 | 3 | 0 | 0 |
| | 2 | 3 | 4 | 0 | 0 |
| Out of range | | 5/20 (25%) | 7/10 (70%) | 0/10 (0%) | 0/10 (0%) |
| Treated | 8 | 2 | 3 | 0 | 0 |
| | 2 | 3 | 2 | 0 | 0 |
| Out of range | | 5/20 (25%) | 5/20 (25%) | 0/20 (0%) | 0/20 (0%) |

*[a]According to ISO 20345 standard for safety shoes (threshold value for tensile strength = 1.2 daN/mm$^2$; (range for elongation = 40%-80%).*

*[b]According to EN ISO 14931 standard for clothing and NF 13336 standard for upholstery (threshold value = 2 daN/mm$^2$).*

*[c]According to ISO 3379 method intended particularly for use with boot and shoe upper leather (threshold value = 5 daN/mm$^2$).*

**Table 1.** Physico-mechanical characteristics of leather at two and eight weeks post-dosing of Banamine Transdermal or saline control.

[1]https://apps.fas.usda.gov

[2]Data on file, Study Reports No. E09-032-01, E09-0331, E09-071-01, E09-072-01, E10-002-01, C10-045-01, E09-058-0

[3]Data on file, Study Report No. S11183-00

IMPORTANT SAFETY INFORMATION: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN. Only for topical use in beef and dairy cattle. Do not use Banamine Transdermal pour-on within 48 hours of expected parturition. Do not use in animals showing hypersensitivity to flunixin meglumine. Cattle must not be slaughtered for human consumption within 8 days of the last treatment. Not 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 born to these cows or heifers. Not for use in suckling beef calves, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Not for use in dairy or beef bulls intended for breeding because reproductive safety has not been evaluated.

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**Product Information**
NADA #141-450, Approved by FDA

# Banamine®
# Transdermal
(flunixin transdermal solution)

Pour-On for Beef and Dairy Cattle
50 mg/mL

**Non-Steroidal Anti-inflammatory Drug**

Only for topical use in beef and dairy cattle. Not for use in beef bulls intended for breeding; dairy bulls; female dairy cattle 20 months of age or older, including dry dairy cows; and suckling beef calves, dairy calves, and veal calves.

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

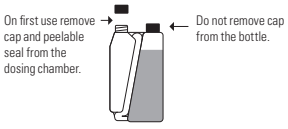
**DESCRIPTION:** Each milliliter of Banamine Transdermal pour-on contains 50 mg flunixin (equivalent to 83 mg flunixin meglumine), 150 mg pyrrolidone, 50 mg L-menthol, 500 mg propylene glycol dicaprylate/dicaprate NF, 0.20 mg FD&C Red No. 40, and glycerol monocaprylate NF qs.

**INDICATIONS:** Banamine Transdermal pour-on is indicated for the control of pyrexia associated with bovine respiratory disease and the control of pain associated with foot rot in steers, beef heifers, beef cows, beef bulls intended for slaughter, and replacement dairy heifers under 20 months of age.

**DOSAGE AND ADMINISTRATION:** Apply only once at a dose of 3.3 mg flunixin per kg body weight (1.5 mg/lb; 3 mL per 100 lbs) topically in a narrow strip along the dorsal midline from the withers to the tailhead. Round all doses up to the nearest weight increment on the dosing chamber. Do not treat cattle if the hide is wet or may get wet in the six hours after dosing because effectiveness has not been evaluated under wet hide conditions.

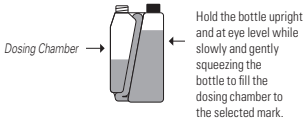
Practice the Administration and Overfill Reduction Instructions a few times to become familiar with operating the package before dosing animals.

**Step 1**

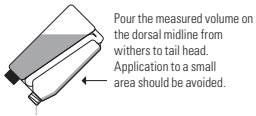



*If the dosing chamber is overfilled, follow the Overfill Reduction Instructions.*

**Step 2**



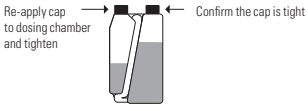

**Step 3**



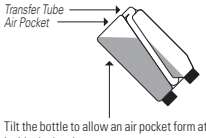

A small amount of liquid will remain on the walls of the chamber, but the chamber is calibrated to account for this.

**OVERFILL REDUCTION INSTRUCTIONS**

**Step 1**

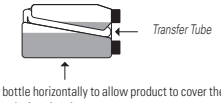



**Step 2**



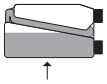

Tilt the bottle to allow an air pocket form at the beginning of the transfer tube inside the bottle.

**Step 3**



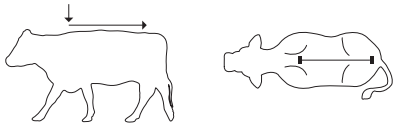

Hold the bottle horizontally to allow product to cover the end of the transfer tube inside the dosing chamber

**Step 4**



Squeeze and release the bottle repeatedly. Product will return to the bottle through the transfer tube.

**Figure 1 –** *Recommended pour-on location*



**CONTRAINDICATIONS:** NSAIDs inhibit production of prostaglandins which are important in signaling the initiation of parturition. The use of flunixin can delay parturition and prolong labor which may increase the risk of stillbirth. Do not use Banamine Transdermal pour-on within 48 hours of expected parturition. Do not use in animals showing hypersensitivity to flunixin meglumine.

**USER SAFETY WARNINGS:** Not for use in humans. Keep out of reach of children. Flunixin transdermal solution is a potent non-steroidal anti-inflammatory drug (NSAID), and ingestion may cause gastrointestinal irritation and bleeding, kidney, and central nervous system effects.

This product has been shown to cause severe and potentially irreversible eye damage (conjunctivitis, iritis, and corneal opacity) and irritation to skin in laboratory animals. Users should wear suitable eye protection (face shields, safety glasses, or goggles) to prevent eye contact; and chemical-resistant gloves and appropriate clothing (such as long-sleeve shirt and pants) to prevent skin contact and/or drug absorption. Wash hands after use.

**In case of accidental eye contact, flush eyes immediately with water and seek medical attention.** If wearing contact lenses, flush eyes immediately with water before removing lenses. **In case of accidental skin contact and/or clothing contamination, wash skin thoroughly with soap and water** and launder clothing with detergent. **In case of ingestion do not induce vomiting and seek medical attention immediately.** Probable mucosal damage may contraindicate the use of gastric lavage. Provide product label and/or package insert to medical personnel.

**RESIDUE WARNINGS:** Cattle must not be slaughtered for human consumption within 8 days of the last treatment. Not 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 born to these cows or heifers. Not for use in suckling beef calves, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

**PRECAUTIONS:** As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal, and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Patients at greatest risk for adverse events are those that are dehydrated, on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Banamine transdermal should be used with caution in animals with suspected pre-existing gastric erosions or ulcerations. Concurrent administration of other NSAIDs, corticosteroids, or potentially nephrotoxic drugs should be avoided or used only with careful monitoring because of the potential increase of adverse events.

NSAIDs are known to have potential effects on both parturition (see Contraindications) and the estrous cycle. There may be a delay in the onset of estrus if flunixin is administered during the prostaglandin phase of the estrous cycle. NSAIDs are known to have the potential to delay parturition through a tocolytic effect. The use of NSAIDs in the immediate postpartum period may interfere with uterine involution and expulsion of fetal membranes. Cows should be monitored carefully for placental retention and metritis if Banamine Transdermal pour-on is used within 24 hours after parturition.

Not for use in dairy or beef bulls intended for breeding because reproductive safety has not been evaluated.

**CLINICAL PHARMACOLOGY:** Flunixin meglumine is a non-steroidal, anti-inflammatory drug. It is a weak acid (pKa=5.82)[1] which exhibits a high degree of plasma protein binding (approximately 99%).[2] However, free (unbound) drug appears to readily partition into body tissues (Vss predictions range from 297 to 782 mL/kg).[2-5] In cattle, elimination occurs primarily through biliary excretion.

Flunixin persists in inflammatory tissues[6] and is associated with anti-inflammatory properties which extend well beyond the period associated with detectable plasma drug concentrations.[4,6] Therefore, prediction of drug concentrations based upon the estimated plasma terminal elimination half-life will likely underestimate both the duration of drug action and the concentration of drug remaining at the site of activity.

Pharmacokinetic properties of flunixin transdermal solution in cattle administered at a dose of 2.5 mg/kg, are summarized in Table 1, comparing results between animals that were allowed to self- and allo-lick vs. animals that were prevented from licking. Animals that were allowed to self- or allo-lick had lower rate and extent of absorption when compared to the animals prevented from licking. However, no dose adjustment is needed to account for the effect of licking because the substantial evidence of effectiveness was demonstrated in animals that were allowed to lick.

Table 1. Average (+/- standard deviation [SD]) PK parameters after a single administration of flunixin transdermal solution at a dose of 2.5 mg/kg in cattle that were either allowed to lick or prevented from allo- and self-licking (n = 24/group).

| PK parameter | Non-licking | | Licking | |
|---|---|---|---|---|
| | Mean | ± SD | Mean | ± SD |
| $C_{max}$ (ng/mL) | 1496 | 769 | N/A | N/A |
| Concentration at 2 h* | 1282 | 533 | 1072 | 353 |
| $T_{max}$ (h) | 1.29 | 0.464 | N/A | N/A |
| $AUC_{2\text{-last}}$ (ng*h/mL) | 7499 | 2131 | 6827 | 4672 |
| $T_{1/2}$ (h) | 8 | 2 | 9 | 6 |

* First blood level in the licking group was taken at 2 hours post-dose.
First blood sample in non-licking group was taken at 0.25 hours post-dose.
$C_{max}$: Maximum observed plasma concentration
$T_{max}$: Time at which $C_{max}$ was observed
$AUC_{2\text{-last}}$: Area under the plasma concentration versus time curve measured between 2 hours and the time of the last quantifiable concentration
$T_{1/2}$: Terminal elimination half-life

Absorption of flunixin transdermal solution in cattle is dependent on environmental temperature. The effect of temperature on flunixin absorption was tested in temperatures ranging from 15.3 to 20.1 °F (average low in the coldest study) to 80 to 100 °F (average high in the warmest study). Flunixin concentrations were consistently lower when the pour-on product was administered in a cold (temperature) rather than hot (temperature) environment. However, the clinical effectiveness was demonstrated over the range of environmental conditions expected under field conditions. No dose adjustments are necessary due to environmental temperature.

**References:**


1. Johansson M, Anler EL. Gas chromatographic analysis of flunixin in equine urine after extractive methylation. *J Chromatogr.* 1988; 427:55-66.
2. Odensvik K, Johansson M. High-performance liquid chromatography method for determination of flunixin in bovine plasma and pharmacokinetics after single and repeated doses of the drug. *Am J Vet Res.* 1995; 56:489-495.
3. Anderson KL, Neff-Davis CA, Davis LE, Bass VD. Pharmacokinetics of flunixin meglumine in lactating cattle after single and multiple intramuscular and intravenous administrations. *Am J Vet Res.* 1990; 51:1464-1467.
4. Odensvik K. Pharmacokinetics of flunixin and its effect on prostaglandin F2∝ metabolite concentrations after oral and intravenous administration in heifers. *J Vet Pharmacol Ther.* 1995;18:254-259.
5. Hardee GE, Smith JA, Harris SJ. Pharmacokinetics of flunixin meglumine in the cow. *Res Vet Sci.* 1985; 39:110-112.
6. Lees P, Higgins AJ. Flunixin inhibits prostaglandin E2 production in equine inflammation. *Res Vet Sci.* 1984; 37:347-349.


**TARGET ANIMAL SAFETY:** In a target animal safety study in 32 six-month old beef cattle (16 castrated males and 16 females), flunixin transdermal solution was administered topically at 3.3, 9.9, and 16.5 mg/kg body weight (1X, 3X, and 5X the labeled dose) on Days 1, 2, and 3 (3X the labeled administration frequency). Cattle were continuously restrained to prevent licking. In addition, the study was conducted under warm environmental conditions (70 °F to 80 °F on dosing days). One animal in the 3X group and three animals in the 5X group exhibiting twisting, kicking, rubbing on the fence, and or prancing, starting 5 to 15 minutes after dosing and lasting up to an hour after dosing on both Days 2 and 3. Two 5X animals had positive fecal occult blood on one of three post-treatment days, and one 5X animal had positive fecal occult blood on Days 2 and 3 post-treatment. Trace occult blood was found in the urine of three animals: one 5X animal on Day 1, one 5X animal on Day 3, and one 3X animal on Day 3. Test article-related pathology changes included a dose-related increase in the incidence and severity of abomasal erosions and ulcerations; and inflammatory cell infiltrates, epidermal necrosis, and small areas of dermal necrosis at the application site. The abomasal lesions correlated with fecal occult blood in three 5X animals. There were no animals with any other evidence of gastrointestinal bleeding or clinical signs of abomasal ulceration during the study.

Application site reactions, including dandruff/skin flakes, hair damage (thin, broken, brittle hair), and skin thickening were observed in effectiveness and/or supportive studies. The application site reactions were first observed around three to seven days post-dosing and lasted for about 14 days. These reactions were cosmetic in nature and generally resolved without treatment.

A pharmacokinetic evaluation demonstrated that the systemic exposure of flunixin is markedly lower when administered transdermally at a dose of 3.3 mg flunixin/ kg BW than when administered intravenously at a dose of 2.2 mg flunixin/kg BW, therefore, female reproductive safety is supported by reproductive safety studies conducted for the approval of BANAMINE (flunixin meglumine injection) in cattle, NADA 101-479.

**EFFECTIVENESS:** Pharmacokinetic studies established that the absorption of flunixin administered transdermally to cattle is highly dependent on environmental temperature. Therefore the effectiveness of flunixin transdermal solution for the control of pyrexia associated with bovine respiratory disease was demonstrated under a range of environmental temperatures in two studies: a field study conducted at four geographic locations (California, Kansas, Nebraska, and Texas) under moderate environmental temperatures (average temperatures ranged from 42 °F to 74 °F on enrollment days) and a field study conducted at a single site (Nebraska) under cold environmental conditions (average temperatures ranged from 2 °F to 20 °F on enrollment days). In both studies, cattle were housed in groups and were not prevented from licking.

In both studies, cattle exhibiting clinical signs of BRD and having a rectal temperature of at least 104.5 °F were enrolled. A total of 235 cattle in the multi-location field study and 50 cattle at the single site field study were administered either flunixin transdermal solution (3.3 mg/kg BW) or an equivalent volume of dyed saline as a pour-on once on Day 0. Six hours after treatment, rectal temperatures were measured. The treatment success rate of the flunixin transdermal solution-treated group was compared to the treatment success rate in the dyed saline-treated group. A treatment success was defined as a drop in rectal temperature of 2 °F in an individual animal. In the multi-location study, the treatment success rate was significantly different ($p < 0.0001$) and higher for the flunixin transdermal solution-treated group (70/120, 58.3%) compared to the dyed saline-treated control group (7/115, 6.1%). In the single site study, the treatment success rate was significantly different ($p = 0.0002$) and higher for the flunixin transdermal solution-treated group (19/25, 76%) compared to the dyed saline-treated control group (4/25, 16%).

The effectiveness of flunixin transdermal solution for the control of pain associated with foot rot in beef and dairy cattle was demonstrated under a range of environmental temperatures in two studies: an induced infection model study conducted in Nebraska with temperatures ranging from 61 °F to 85 °F on the day of enrollment and treatment; and an induced infection model study conducted in Kansas with temperatures ranging from 27 °F to 53 °F on the day of enrollment and treatment. In both studies, cattle from both treatment groups were commingled in pens and were not prevented from licking.

In each study, cattle were challenged by subcutaneous injection of a culture of *Fusobacterium necrophorum* into the interdigital space of the right front foot using a method that was validated to induce pain representative of foot rot. Cattle were enrolled when they demonstrated signs of pain associated with foot rot based on lameness, interdigital lesion, and interdigital swelling criteria. Pressure mat gait parameters maximum total force (kgf) and contact area ($cm^2$) were also measured at enrollment. A total of 30 cattle at each site were administered either flunixin transdermal solution (3.3 mg/kg BW) or an equivalent volume of dyed saline as a pour-on once on Day 0. Six hours after treatment, lameness scores and pressure mat gait parameters maximum total force and contact area were measured.

Effectiveness was determined independently at each site based on treatment success rates at six hours after treatment; and the change in maximum total force and contact area between enrollment and six hours after treatment. A treatment success was defined as a decrease in lameness score by ≥1 (scale 1 to 5, with enrollment of animals with lameness score ≥3) from the enrollment lameness score. The treatment success rate of the flunixin transdermal solution-treated group was compared to the treatment success rate in the dyed saline-treated group at both sites.

Changes in biometric gait parameters were also compared between the treatment groups.

In the Nebraska study, the treatment success rate was significantly different and higher for the flunixin transdermal solution-treated group (15/15, 100%)compared to the dyed saline-treated group (1/15, 6.67%); and the mean change in maximum total force and mean change in contact area were statistically significantly different ($p < 0.0001$) and higher in the flunixin transdermal solution-treated group (43.08 kgf and 16.76 $cm^2$) compared to the dyed saline-treated control group (-4.14 kgf and -2.70 $cm^2$). In the Kansas study, the treatment success rate was significantly different ($p = 0.0387$) and higher for the flunixin transdermal solution-treated group (14/15, 93.33%) compared to the dyed saline-treated group (8/15, 53.33%); and the mean change in maximum total force and mean change in contact area were statistically significantly different ($p = 0.0002$ and $p < 0.0001$, respectively) and higher in the flunixin transdermal solution-treated group (34.32 kgf and 16.38 $cm^2$) compared to the dyed saline-treated control group (-0.54 kgf and -0.96 $cm^2$).

**CONTACT INFORMATION:** For technical assistance or to report a suspected adverse drug experience, call: 1-800-219-9286. For customer service or to request a Safety Data Sheet (SDS), call: 1-800-211-3573. For additional Banamine Transdermal pour-on information go to www.BanamineTD.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

**HOW SUPPLIED:** Banamine Transdermal pour-on, is available in 100-mL (NDC 0061-4363-01), 250-mL (NDC 0061-4363-02), and 1-L (NDC 0061-4363-03) bottles.

**STORAGE INFORMATION: Store at or below 30°C (86°F). Use within 6 months of first opening.**

**For Patent information:** http://www.merck.com/product/patent/home.html.
NADA 141-450, Approved by FDA. Use Only as Directed.  Made in Germany. Distributed by: Intervet Inc. d/b/a Merck Animal Health, Madison, NJ 07940

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