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Exzolt® Cattle-CA1
(fluralaner topical solution)
IT'S MORE THAN
A BREAKTHROUGH.
A first-of-its-kind FDA conditionally approved pour-on for **New World screwworm** and **cattle fever tick.**
MERCK
Animal Health
This image contains content generated using artificial intelligence (AI).

Exzolt® Cattle-CA1
(fluralaner topical solution)

A FIRST-OF-ITS-KIND
ECTOPARASITICIDE FOR BEEF CATTLE

EXZOLT® CATTLE-CA1 (fluralaner topical solution) delivers a powerful new tool to protect cattle against deadly parasites. Fluralaner, the active ingredient, represents a breakthrough in parasite management as the first isoxazoline-class ectoparasiticide for use in U.S. beef cattle.

With a novel mode of action and no known resistance, EXZOLT CATTLE-CA1 delivers fast-acting protection.

NEW PRESCRIPTION PRODUCT

EXZOLT CATTLE-CA1 is the first and only ectoparasiticide conditionally approved by the FDA for both New World screwworm and cattle fever tick in cattle.

- EXZOLT CATTLE-CA1 is conditionally approved for use in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age.
- Do not use in bulls intended for breeding 1 year of age and older, dairy calves and veal calves.

*Source

This innovation underscores Merck Animal Health's commitment to equipping veterinarians and beef producers with the tools they need to protect animal health, enhance productivity, and ensure well-being.

IMPORTANT SAFETY INFORMATION: Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-617. It is a violation of Federal law to use this product other than as directed in the labeling. Not for use in humans. Keep out of reach of children. Accidental exposure may cause skin and eye irritation. Highly flammable. Keep away from heat, sparks, open flame or other sources of ignition. Use only for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) and treatment and control of cattle fever tick (*Rhipicephalus microplus*) in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in bulls intended for breeding 1 year of age and older, dairy calves, and veal calves. Cattle must not be slaughtered for human consumption within **98 days** of treatment. If cattle are continuously exposed to temperatures at or above 60°F after product administration, then cattle may be slaughtered for human consumption 44 days after treatment. Violative residues may result if cattle are exposed to temperatures below 60°F after administration and are slaughtered at 44 days. For complete safety information and product dosing instructions, refer to the product label.

*Source - this image was generated by artificial intelligence (AI)

EXTENSIVE RESEARCH WITH FLURALANER

EXZOLT CATTLE-CA1 received FDA conditional approval based on a reasonable expectation of effectiveness, supported by published studies and Merck Animal Health research.[1] The active ingredient, fluralaner, has demonstrated safety and efficacy across species in over 170 global clinical studies and is approved in 93 markets.

EASY TO APPLY

The prescription product is administered as a pour-on. It circulates in the bloodstream and breaks the lifecycle of the parasites, defending cattle against infestations.

EASY TO DOSE

The pre-calibrated packaging helps ensure the right dose is given every time. The 1 L bottle design allows for proper topical application along the animal's back. The 5 L is administered with an EXZOLT CATTLE-CA1 applicator. The blue-colored solution makes it simple to accurately and quickly measure the dose volume for each animal.

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PROTECT AGAINST DANGEROUS PARASITES

New World screwworm (NWS) and cattle fever tick (CFT) are dangerous parasites that can cause major economic losses and significantly impact animal welfare and productivity. The cattle industry must remain vigilant to minimize impacts. Merck Animal Health is dedicated to providing veterinarians and producers with tools to address these significant ectoparasite issues and support animal health.

PROOF FROM THE FIELD

COMBAT NEW WORLD SCREWWORM AND CATTLE FEVER TICK WITH EXZOLT CATTLE-CA1

Results from field trials demonstrate that EXZOLT CATTLE-CA1 provides veterinarians and cattle producers with a novel tool to address the significant threat of these ectoparasites.[1]

Trials summary for NWS

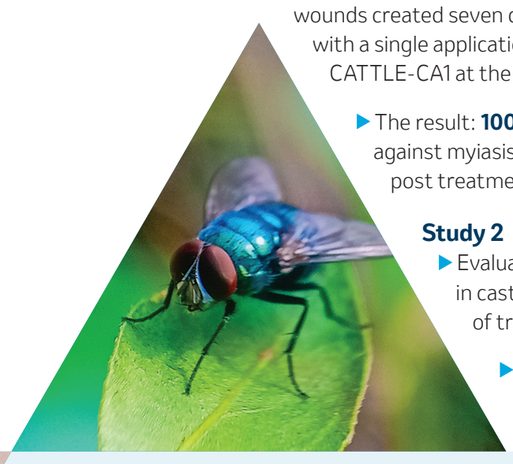
- Demonstrated strong prevention and treatment efficacy against NWS infestations.

Trials summary for CFT

- Safely and effectively controlled and treated CFT infestations.

NEW WORLD SCREWWORM

EXZOLT CATTLE-CA1 has been evaluated in three separate studies for its effectiveness in both preventing and treating NWS infestation.[1] Two studies were conducted to evaluate its effectiveness to prevent NWS infestation. Both studies demonstrated strong preventative efficacy against NWS. An additional study evaluated the effectiveness of EXZOLT CATTLE-CA1 to treat NWS infestation.



PREVENTION STUDIES:

Study 1

- Evaluated prevention of NWS infestation in wounds created seven days post-treatment with a single application of EXZOLT CATTLE-CA1 at the dose of 2.5 mg/kg BW.
- The result: **100% efficacy** against myiasis for at least 14 days post treatment.

Study 2

- Evaluated prevention of NWS infestation in castration wounds created on the day of treatment.
- The result: **100% efficacy** against myiasis for up to 14 days following castration.

TREATMENT STUDY:

- Surgical wounds were created and left exposed to allow NWS infestation. Eggs or larvae were confirmed three days later. Animals then received a single dose of EXZOLT CATTLE-CA1 (2.5 mg/kg BW).
- One study resulted in **100% therapeutic anti-myiasis efficacy by Day 3** and continued until Day 7, the end of the study.

CATTLE FEVER TICK

EXZOLT CATTLE-CA1 has been evaluated in multiple field studies for its effectiveness against *Rhipicephalus microplus*, the cattle fever tick.

Currently, options to address cattle fever tick infestations are limited. EXZOLT CATTLE-CA1 provides a novel solution for the control and treatment of cattle fever tick infestations in U.S. cattle.

STUDY RESULTS:

- Results of two efficacy studies that were conducted in Australia and Brazil demonstrated that a single dose of **EXZOLT CATTLE-CA1 was effective in control of a natural infestation of CFT for up to 56 days.**[2]

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UNDERSTAND AND IDENTIFY NEW WORLD SCREWWORM (NWS)

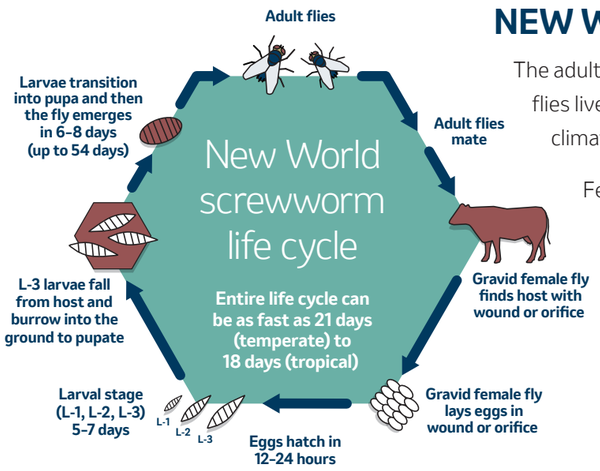
New World screwworm (NWS) is endemic in Cuba, Haiti, the Dominican Republic and countries in South America.[3] Although NWS was eradicated from the United States in 1966, detection of the NWS fly north of the biological border that has contained it to South America for decades presents a potentially devastating threat to the U.S. cattle industry.

A contemporary outbreak of NWS could cost producers $4.3 billion per year and cause a total economic loss of more than $10.6 billion.[4]

WHAT IS NEW WORLD SCREWWORM?

New World screwworm fly (*Cochliomyia hominivorax*) is a species of parasitic blowfly whose larvae feed on the live tissue of warm-blooded animals, causing a serious and potentially deadly condition known as **myiasis.**

Myiasis is the parasitic infestation of the body of a live animal by fly larvae (maggots) that grow inside the host while feeding on live tissue. NWS can impact livestock, pets, wildlife such as deer and other warm-blooded mammals.



NEW WORLD SCREWWORM LIFE CYCLE

The adult female NWS fly mates once and lives about 10 days, while male flies live two to three weeks and mate multiple times. They prefer warm climates and cannot survive sustained temperatures below 46°F.

Female NWS flies lay eggs at the edge of a wound or mucosal opening such as the nose, ear, mouth or genitalia of a warm-blooded mammal. Wounds as small as a tick bite can attract them. After hatching, NWS larvae (maggots) burrow into their host in a screw-like pattern as they feed on the living tissue.

WHAT TO LOOK FOR

Surveillance of your animals is crucial to detect and treat NWS infestations before significant, potentially fatal, damage is done. The following signs may indicate that an animal needs further evaluation and treatment[5]:

- Irritated or depressed behavior.
- Head shaking.
- Presence of maggots in wound.
- Go off feed.
- Self-isolate from herd.
- Bloody discharge or foul odor from wound.

NWS larvae can burrow deep into the living flesh, so an animal may exhibit a small surface wound with a larger pocket of larvae beneath and other species of maggots visible around the opening.

WHAT TO DO IF YOU SUSPECT AN INFESTATION

If you suspect a NWS infestation, contact your veterinarian immediately. Suspected cases must be reported to APHIS and state animal health officials. Visit www.aphis.usda.gov for reporting procedures.

PREVENTION AND CONTROL

Work closely with your veterinarian to prevent and treat NWS infestations. NWS female flies are drawn to wounds to lay their eggs. NWS infestations are more likely to occur around management practices such as castration and dehorning.[5] To the extent possible, eliminate or delay any procedure that will result in a wound. EXZOLT CATTLE-CA1 can help prevent NWS infestations.

Wounds will likely need to be thoroughly cleaned and all visible larvae removed. Antiseptics may be used to prevent secondary infections. Your veterinarian may prescribe an approved treatment, such as EXZOLT CATTLE-CA1, to eliminate remaining larvae.

A CONTEMPORARY OUTBREAK OF NWS COULD COST PRODUCERS $4.3 BILLION PER YEAR AND CAUSE A TOTAL ECONOMIC LOSS OF MORE THAN $10.6 BILLION.[4]

Be vigilant for signs of New World screwworm in local livestock, wildlife and pets. Adult NWS flies are slightly larger than house flies, with red or orange eyes, metallic blue or green bodies and three dark stripes on their back. Their egg packets form a shingle-like pattern at wound edges, unlike the haystack pattern of the secondary screwworm (*Cochliomyia macellaria*). NWS larvae appear within three days of hatching.

If you believe you have found evidence of a screw-worm infestation, report it immediately.

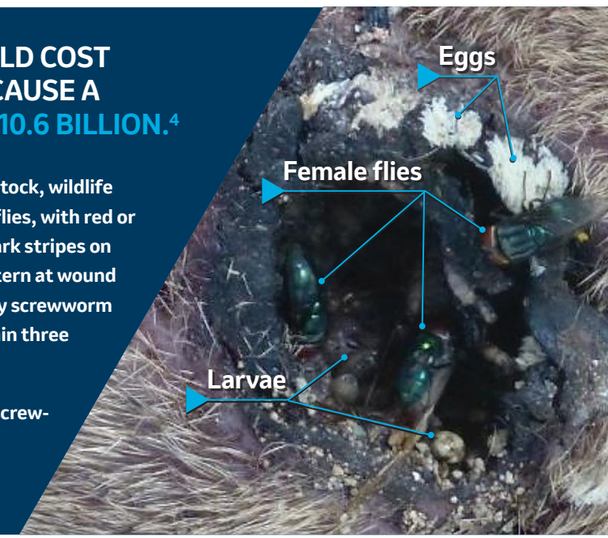


Photo from www.aphis.usda.gov

Exzolt® Cattle-CA1
(fluralaner topical solution)

UNDERSTAND AND IDENTIFY CATTLE FEVER TICK (CFT)

Cattle fever ticks (*Rhipicephalus microplus*) are dangerous parasites responsible for major economic losses, including transmitting babesiosis in cattle. Cattle fever ticks (CFT) were eradicated from the U.S. in 1943 except in a permanent quarantine zone along the Texas/Mexico border where the presence of CFT poses a significant biosecurity risk.[6]

Before eradication, cattle fever tick infestations were the cause of indirect and direct losses totaling an estimated $130.5 million — the equivalent of $3 billion today.[6]

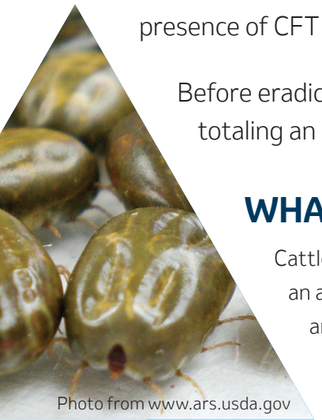


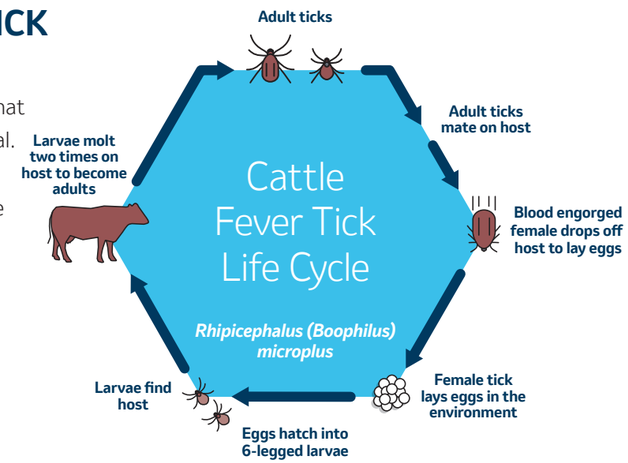
Photo from www.ars.usda.gov

WHAT IS CATTLE FEVER TICK?

Cattle fever tick (*Rhipicephalus microplus*) is a hard tick that attaches itself to the skin inside an animal's thighs, flanks and forelegs or along the belly and brisket. CFT are capable of carrying and spreading the protozoa, or microscopic parasites, *Babesia bovis* and *Babesia bigemina* that cause babesiosis, commonly known as cattle fever. CFT primarily infests cattle but can also be found on horses, sheep and other animals sharing the environment with cattle.

CATTLE FEVER TICK LIFE CYCLE

R. microplus is a single-host tick that completes its life cycle on one animal. It contracts *Babesia* protozoa from infected hosts and transmits it to larvae during mating.[7] After feeding, engorged females drop off, lay 2,000 to 4,000 eggs, and die, while males mate with multiple females. The hatched larvae then climb onto new hosts from vegetation, continuing the infection cycle.



WHAT TO LOOK FOR

Babesia bovis attacks and destroys red blood cells.[7] Cattle suffering from cattle fever will exhibit clinical signs such as:

- Acute anemia.
- High fever.
- Rapid breathing.
- Weight loss.
- Decreased milk production.
- Visible ticks.
- Sudden death.

WHAT TO DO IF YOU SUSPECT AN INFESTATION

If you suspect a CFT infestation, contact your veterinarian immediately. Suspected cases must be reported to APHIS and state animal health officials. Visit www.aphis.usda.gov for reporting procedures.

TREATMENT AND CONTROL

Work closely with your veterinarian when bringing new animals into your herd or if you suspect CFT. After buying livestock, do not commingle them with your existing herd until you are sure that they are free of diseases and pests. Early reporting can help prevent ticks from establishing a large population.

If cattle fever ticks are found on your animals, your veterinarian and state animal health officials will work closely with you to determine the best treatment and control plan. This may include dipping, vacating a premises or treatment with an approved ectoparasiticide such as EXZOLT CATTLE-CA1.

Exzolt® Cattle-CA1
(fluralaner topical solution)

DOSING, ADMINISTRATION AND STORAGE

Cattle producers should work with their veterinarian to determine when to apply EXZOLT CATTLE-CA1 and always follow the label.

For New World screwworm treatment, apply one dose for active infestations. For prevention, use immediately at wound creation (e.g., castration, dehorning). For cattle fever tick treatment and control, apply to new arrivals under your veterinarian's guidance.

EXZOLT CATTLE-CA1 is available from licensed veterinarians.

DOSING AND ADMINISTRATION

- Product handlers should wear protective gloves and take care to avoid skin and eye exposure.
- Administer as a pour-on at 1 mL per 44 pounds of body weight, applied along the dorsal midline from withers to tailhead. Add 2.5 mL for each 110 pounds above 1,320 pounds of body weight. For the 1 L presentation, squeeze the product into the dosing chamber to measure total volume needed. For the 5 L presentation, use the provided dosing gun.
- To ensure the administration of a correct dose, body weight should be determined as accurately as possible.
- EXZOLT CATTLE-CA1 should be applied to dry skin. Animals should not be exposed to extreme heat or open flame after administration of the product.

STORAGE

- Store the product in its original packaging, in a cool, dry place, at room temperature (between 59°F and 86°F), away from sunlight and out of the reach of children and pets.
- After opening the bottle, store the product at room temperature (between 59°F and 86°F) and use it within a maximum period of six months.
- Keep product away from heat, sparks, open flame or other sources of ignition.

⚠ DRESS RIGHT FOR THE JOB

Users should wear eye protection, such as safety glasses or goggles, to prevent eye contact. Chemical resistant gloves and appropriate clothing, such as a long-sleeved shirt and pants, should be worn to prevent skin contact and/or drug absorption. Wash hands after use. Keep product away from heat, sparks, open flame or other sources of ignition including branding irons.

FREQUENTLY ASKED QUESTIONS

What product presentations are available?
EXZOLT CATTLE-CA1 will be available in 1 L or 5 L presentations. Each product presentation supports accurate dosing — either through the pre-calibrated packaging of the 1 L bottle or the EXZOLT CATTLE-CA1 applicator available with the 5 L presentation.

How long should animals be protected from rain exposure after dosing?
EXZOLT CATTLE-CA1 should be applied to dry skin. Do not treat cattle if their hide is wet or they might get wet within six hours of dosing.

What is the slaughter withdrawal period?
Cattle must not be slaughtered for human consumption within **98 days** of treatment. If cattle are continuously exposed to temperatures at or above 60°F after product administration, then cattle may be slaughtered for human consumption 44 days after treatment. Violative residues may result if cattle are exposed to temperatures below 60°F after administration and are slaughtered at 44 days.

Can this product be given to lactating dairy cows?
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 calves born to these cows or heifers.

Will parasites develop resistance to EXZOLT CATTLE-CA1?
Currently, no resistance is known. A comprehensive parasite control strategy helps delay resistance.

What does conditional approval mean?
EXZOLT CATTLE-CA1 is conditionally approved by the FDA pending completion and approval of all efficacy data. EXZOLT CATTLE-CA1 has a reasonable expectation of effectiveness in cattle based on published studies and Merck Animal Health research.[1]

Is Merck Animal Health taking steps for full approval?
Yes. Conditional approval lasts one year and can be renewed annually for up to five years. To renew, Merck Animal Health must show progress toward proving full effectiveness. The company is actively conducting research and submitting data to the FDA.

Can it be used off-label?
Off-label use is prohibited. It is a violation of federal law to use EXZOLT CATTLE-CA1 other than as directed in the labeling.

What should I do if I suspect New World screwworm or cattle fever tick?
Contact your veterinarian immediately. Suspected cases must be reported to APHIS and state animal health officials. Visit www.aphis.usda.gov for reporting procedures.

VISIT EXZOLTCATTLE-CA1.COM TO LEARN MORE

1. EXZOLT® CATTLE-CA1. Product label. Merck Animal Health; 2025.
2. Merck Animal Health final study report AUS-CFT Study 5 and BRZ-CFT Study 6.
3. United States Department of Agriculture. Animal and Plant Health Inspection Service. (2025, August 6). New World Screwworm. https://www.aphis.usda.gov/livestock-poultry-disease/cattle/ticks/screwworm
4. American Veterinary Medical Association. (2025, August 21). US steps up response to screwworm threat. *AVMA News*. https://www.avma.org/news/us-steps-response-screwworm-threat
5. United States Department of Agriculture, Animal and Plant Health Inspection Service. (2025, April). *New World Screwworm: Be aware and prepare (Information for veterinarians)* [PDF]. https://www.aphis.usda.gov/sites/default/files/factsheet-nws-private-veterinarians.pdf
6. United States Department of Agriculture. Animal and Plant Health inspection Service. Animal and Plant Health Inspection Service. (2025, August 12). Cattle fever ticks. https://www.aphis.usda.gov/livestock-poultry-disease/cattle/ticks/cattle-fever
7. Texas Animal Health Commission. *Cattle fever tick fact sheet* [PDF]. https://www.tahc.texas.gov/news/brochures/TAHCFactsheet_FeverTick.pdf

Exzolt® Cattle-CA1
(fluralaner topical solution)

Antiparasitic

50 mg of fluralaner/mL

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

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-617.

It is a violation of Federal law to use this product other than as directed in the labeling.

DESCRIPTION: Exzolt Cattle-CA1 (fluralaner topical solution) contains fluralaner, an antiparasitic of the isoxazoline class. Each mL of Exzolt Cattle-CA1 contains 50 mg of fluralaner.

The chemical name of fluralaner is (±)-4-[5-(3,5-dichlorophenyl)-5-(trifluoromethyl)-4,5-dihydroisoxazol-3-yl]-2-methyl-N-[2-oxo-2-(2,2,2-trifluoroethylamino)ethyl]benzamide. Inactive Ingredients: pyrrolidone, isopropyl alcohol, l-menthol, propylene glycol dicaprylate/dicaprate, FD&C blue No. 1, FD&C yellow No. 5.

INDICATIONS FOR USE: Exzolt Cattle-CA1 is indicated for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) and treatment and control of cattle fever tick (*Rhipicephalus microplus*) in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in bulls intended for breeding 1 year of age and older, dairy calves, and veal calves.

DOSAGE AND ADMINISTRATION: Exzolt Cattle-CA1 is a ready-to-use topical formulation intended for direct application to the hair and skin in a narrow strip extending along the dorsal midline from the withers to the base of the tail (see Figure 1). The recommended rate of administration is 1 mL/44.1 lbs. (1 mL/20 kg) body weight, which is equivalent to 1.13 mg of fluralaner for each pound (2.5 mg/kg) body weight. Effectiveness has not been evaluated in cattle with wet hides.

Recommended site of administration:

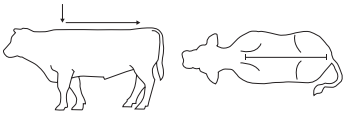


Figure 1: Recommended location for the topical application in a narrow strip along the dorsal midline from the withers to the base of the tail.

Administration of the product with 250 mL and 1L bottles with built-in dosing chamber: To ensure administration of a correct dose, body weight should be determined as accurately as possible, and accuracy of the dosing volume should be checked before administration. Round the dose up to the nearest volume increment on the dosing chamber, which goes up in 2.5 mL increments.

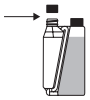
The table below can be consulted to assist in the calculation of the appropriate volume which must be applied based on the weight of animal being treated.

Body Weight (Pounds)	Dose Volume (mL)
220	5
330	7.5
440	10
550	12.5
660	15
770	17.5
880	20
990	22.5
1100	25
1320*	30

*Add 2.5 mL for each 110 pounds above 1320 pounds of body weight.

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

Step 1
On first use remove cap and peelable seal from the dosing chamber.

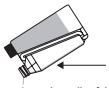


Do not remove cap from the bottle.

Step 2

Hold the bottle upright and at eye level while slowly and gently squeezing the bottle to fill the dosing chamber to the selected mark.

Step 3



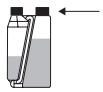
Pour the measured volume on the dorsal midline from withers to the base of the tail. Application to a small area should be avoided.

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

Avoid squeezing the container section while the solution is poured from the dosing chamber.

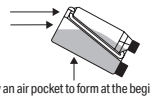
If the dosing chamber is overfilled follow the Overfill Reduction Instructions below:

Step 1
Re-apply cap to dosing chamber and tighten.



Confirm the cap is tight.

Step 2



Tilt the bottle to allow an air pocket to 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.

Administration of the product with 5L bottle with an applicator device: These bottles are designed for use with the Simcro Breaze™ Applicator Device (30 mL). This applicator device and delivery tubing (sold separately by Simcro as a kit) should be used with the 5L bottle. The 5L bottle is supplied with spigot cap attached to dip tube for its use with the applicator device. A strap is also included for use of the 5L bottle as a backpack.

To ensure administration of a correct dose, body weight should be determined as accurately as possible, and accuracy of the dosing volume should be checked before administration. Round the dose up to the nearest volume increment on the applicator device, which goes up in 1 mL increments.

The table below can be consulted to assist in the calculation of the appropriate volume which must be applied based on the weight of animal being treated.

Body Weight (Pounds)	Dose Volume (mL)
220	5
440	10
660	15
880	20
1100	25
1320*	30

*Add 1 mL for each 44 pounds above 1320 pounds of body weight.

Assembly, Disassembly and Cleaning Instructions for the 5L bottle with applicator device:

Step 1
Follow the applicator device manufacturer's assembly directions. Connect one end of the delivery tubing to the connection point on the dosing applicator.

Step 2
Remove the transit cap and protection seal from the 5L bottle and replace with spigot cap attached to dip tube. Tighten spigot cap to bottle and attach other end of delivery tubing to the spigot cap. Do not discard the transit cap until the contents of the 5L bottle are completely used. Please refer to Figure 2 for the assembled 5L bottle with applicator device.

Step 3
Keeping the 5L bottle in an upright position, gently prime the applicator device per the included manufacturer's instructions, checking for leaks. With the applicator device in an upward position, expel all visible air from the barrel and confirm that product is visibly expressed from the tip of the applicator device so that it is free of any residual air.

Step 4
Follow the applicator device manufacturer's directions for adjusting the dose.

Step 5
When the interval between uses of the applicator device is expected to exceed 1 week, take off the entire spigot assembly (delivery tubing connected to the spigot cap with attached dip tube while still connected to the applicator device), from the 5L bottle. Return any unused product remaining in the applicator device and in the delivery tubing back into the 5L bottle. Raise the spigot cap with dip tube attached and place the tip of the applicator device into the 5L bottle. Discharge the remaining product from the spigot assembly into the bottle. Place the transit cap onto the 5L bottle to close it. Submerge the dip tube in warm, soapy water. Flush warm soapy water through the delivery tubing and through the applicator device, followed by flushing them with clean water and allowing them to dry. Once dry, store the entire dosing assembly (applicator device, delivery tubing, spigot cap with attached dip tube) in a safe, clean place until next use. Refer to the manufacturer's directions for maintenance of the applicator.

Figure 2. 5L bottle and applicator device with tubing

WARNINGS:

WITHDRAWAL PERIODS AND RESIDUE WARNINGS:

Environmental temperature affects the withdrawal period.

Cattle must not be slaughtered for human consumption within **98 days** of treatment.

If cattle are continuously exposed to temperatures at or above 60° F after product administration, then cattle may be slaughtered for human consumption 44 days after treatment. Violative residues may result if cattle are exposed to temperatures below 60° F after administration and are slaughtered at 44 days.

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 beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

USER SAFETY WARNINGS:
Not for use in humans. Keep out of reach of children.

This drug product is a skin and eye irritant; special care should be taken to avoid contact. Personal protective equipment should be worn, such as gloves, long sleeve shirt and pants, as well as glasses or goggles to prevent skin, eye and mucous membrane contact and/or drug absorption, while handling the product. In case of skin contact, wash with soap and water. If contact with eyes occurs, immediately rinse thoroughly with water. In case of accidental spill, immediately remove affected clothing and wash contacted skin with soap and water. In case of accidental ingestion, immediately rinse the mouth with plenty of water and seek medical advice.

Do not eat, drink, or smoke while handling the product. Wash hands thoroughly with soap and water immediately after use of the product.

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

To obtain a Safety Data Sheet (SDS) or for technical assistance, call Merck Animal Health at 1-800-211-3573.

CONTACT INFORMATION: Contact Merck Animal Health at 1-800-211-3573 or https://www.merck-animal-health-usa.com. To report suspected adverse drug experiences, contact Livestock Technical Service at 1-800-211-3573. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or https://www.fda.gov/reportanimalae.

CLINICAL PHARMACOLOGY

Mechanism of Action: Fluralaner belongs to the class of isoxazoline-substituted benzamide derivatives. Fluralaner is an inhibitor of the arthropod nervous system. The mode of action of fluralaner is the antagonism of the ligand-gated chloride channels (gamma-aminobutyric acid (GABA)-receptor and glutamate-receptor).

Pharmacokinetics: The pharmacokinetic properties of a single 2.5 mg/kg dose of Exzolt Cattle-CA1 administered topically along the dorsal midline from the withers to the base of the tail to cattle that were not restricted from grooming are presented in Table 1 (n = 12).

Table 1. Mean (± standard deviation) plasma pharmacokinetic parameters of total fluralaner[a] after a single topical administration of Exzolt Cattle-CA1 in male and female cattle in warm conditions (54 – 98°F).

Parameter (units)	Estimate
Cmax (ng/mL)	127 ± 82.2
Tmax[b] (day)	5 (4 – 12)
AUC_{0-56} (day*ng/mL)	1570 ± 1220
AUC_{inf} (day*ng/mL)	1590 ± 1230
t½ (day)	8.48 ± 1.84

[a]Although total fluralaner (R+S) is reported, the S enantiomer is more abundant and active than the R

[b]Median and range

Cmax = maximum plasma concentration

Tmax = time to maximum plasma concentration

AUC_{0-56} represents the AUC from day 0 to day 56

AUC_{inf} = area under the curve from the time of dosing extrapolated to infinity

t½ = half-life

TARGET ANIMAL SAFETY

Margin of Safety: In a margin of safety study, Exzolt Cattle-CA1 was well tolerated in 32 six to seven month old healthy beef cattle (16 males and 16 females). Study animals were administered 3.7, 11.1, or 18.5 mg/kg body weight (1X, 3X, and 5X the maximum anticipated labeled dose) of Exzolt Cattle-CA1 by topical application three times 42 days apart (Days 0, 42, and 84). Cattle in the control group (0X) were treated with green dyed sterile saline at a dose volume similar to the 5X treated group. General health observations were conducted twice daily from acclimation to the end of the 98-day study. Variables measured periodically throughout the study for each animal were body weight; physical examinations; neurological examinations; analysis of blood for hematology, clinical chemistry, coagulation, and toxicokinetics; fecal and urine analysis; and feed and water consumption. All animals were necropsied at the end of the study for gross and histopathological examination and select organs were weighed.

Test article-related application site reactions, including skin flaking/scurfing and scabbing were observed. These findings were dose-dependent in both incidence and severity. Reactions in the 1X animals appeared after the second administration. These reactions in the 1X group were cosmetic in nature and did not require treatment.

Female Reproductive Safety: In a reproductive safety study, Exzolt Cattle-CA1 was well tolerated in 200 healthy beef cows between the ages of 3 to 11 years old. Study animals were administered 11.1 mg fluralaner/kg body weight (3X the maximum labeled dose) of Exzolt Cattle-CA1 by a single topical application once during breeding (estrus; before timed-artificial insemination), early in the 1st trimester of pregnancy, during the mid-1st trimester of pregnancy, or in the 3rd trimester of pregnancy. Cattle in the control group (0X) were treated with green dyed sterile saline at a dose volume similar to the treated groups (3X). General health observations were conducted twice daily from acclimation to the end of the study at 30±2 days postpartum. Variables measured at start of acclimation and at the end of the study for each animal were body weight (including prior to each dosing) and physical examinations (including at parturition for offspring). Reproductive safety parameters included conception rate, abortion rate, calving rate, live births, stillborn calves, perinatal death, premature deliveries, neonatal death, dystocia, ability of calf to stand, walk and suckle, and abnormalities. Three stillbirths and one premature delivery were observed in animals in the control group. One stillbirth associated with dystocia and one premature delivery were documented in cows treated with Exzolt Cattle-CA1. Six abortions occurred across three of the Exzolt Cattle-CA1 treated groups (2 out of 31 cows in the estrus-treated group; 2 out of 34 cows in the early first trimester-treated group; 2 out of 27 cows in the mid first trimester-treated group). One calf was found dead within 24 hours of birth in an Exzolt Cattle-CA1 treated cow. These events were considered to occur at rates typical for the source herd and unlikely to be test article related. Not for use in bulls intended for breeding over 1 year of age, as reproductive safety has not been evaluated.

Reasonable Expectation of Effectiveness: A reasonable expectation of effectiveness may be demonstrated based on evidence such as, but not limited to, pilot data in the target species or studies from published literature.

Exzolt Cattle-CA1 is conditionally approved pending a full demonstration of effectiveness. Additional information for Conditional Approvals can be found at www.fda.gov/animalca.

A reasonable expectation of effectiveness for Exzolt Cattle-CA1 for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) and treatment and control of cattle fever tick (*Rhipicephalus microplus*) in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age is based on results from the following foreign studies conducted in Australia, Brazil, and South Africa.

A. New World Screwworm (NWS) (*Cochliomyia hominivorax*)
Three effectiveness studies utilizing natural NWS infestations conducted in Brazil in 2018 are described below:

1. Support for a prevention indication: This study evaluated prevention of New World Screwworm (NWS) myiasis in a surgical wound created seven days after treatment administration. Animals received either a placebo (n=6) or Exzolt Cattle-CA1 (n=6) on Day -7. Seven days later, two surgical incisions were made on each side of the body at the shoulder. Animals were housed outside to facilitate natural infestation of the wounds with NWS. Cattle were monitored twice daily for 10 days post-incision to assess the presence of eggs and larvae. A single topical application of Exzolt Cattle-CA1 at the dose of 2.5 mg/kg provided 100% prevention against myiasis for the length of the study.
2. Support for a prevention indication: This study evaluated prevention of NWS myiasis in a castration wound created on the day of treatment with either a placebo (n=15) or Exzolt Cattle-CA1 (n=15). Animals were housed outside to facilitate natural infestation of the wounds with NWS. Cattle were monitored daily for 14 days post-surgery to assess the presence of eggs, larvae, and the progress of wound healing. A single topical administration of Exzolt Cattle-CA1 at the dose of 2.5 mg/kg provided 100% prevention against myiasis for up to 14 days following castration.
3. Support for a therapeutic indication: This study evaluated the effectiveness of the product to treat a wound already infested with NWS. A surgical wound was created and left exposed to facilitate natural infestation with NWS. Three days later, after confirming the presence of live larvae, animals were treated topically once with either a placebo (n=12) or Exzolt Cattle-CA1 (n=12). A single topical administration of Exzolt Cattle-CA1 at the dose of 2.5 mg/kg achieved 90.9% effectiveness by the second day post-treatment and reached 100% effectiveness by the third day. No myiasis in treated animals was observed up to day 5.

B. Cattle Fever Tick (*Rhipicephalus microplus*)
Three dose confirmation studies conducted in Brazil and South Africa and a rain exposure study conducted in Brazil utilizing induced infestations of *R. microplus* were evaluated. These studies were conducted between 2018 and 2021. In each study, animals were individually housed and randomly assigned to control and Exzolt Cattle-CA1-treated groups. Exzolt Cattle-CA1-treated groups received a single administration at the dose of 2.5 mg/kg. A total of thirty animals were treated with Exzolt Cattle-CA1 across these four studies. The product demonstrated 100% effectiveness within the first week after Exzolt Cattle-CA1 administration. Length of consistent 100% persistent effectiveness ranged from 39 days to approximately 110 days post-treatment.

Thirteen field effectiveness studies conducted in Brazil and Australia utilizing natural infestations of *R. microplus* were evaluated. These studies were conducted between 2017 and 2023. In each study, animals were grouped housed and randomly assigned to control and Exzolt Cattle-CA1-treated groups. Exzolt Cattle-CA1-treated groups received a single administration at the dose of 2.5 mg/kg. Approximately 220 animals were treated with Exzolt Cattle-CA1 across these thirteen studies. The product demonstrated 100% effectiveness within the first week after Exzolt Cattle-CA1 administration. Length of consistent 100% persistent effectiveness ranged from 28 days to 70 days post-treatment.

C. Rain exposure study
One study was conducted to evaluate the impact of simulated rainfall post-treatment on the effectiveness of Exzolt Cattle-CA1 with cattle artificially infested with *R. microplus*. A total of 30 cattle (cross-bred beef bulls) were randomized to one of five groups with six animals each: Groups A, B, C, and D were treated with Exzolt Cattle-CA1 (2.5 mg/kg) and Group E with saline (equivalent volume). Groups A, B, and C were exposed to simulated rainfall at the following post-treatment timepoints: 6 hr, 12 hr, and 24 hr, respectively. Groups D and E had no exposure to rain. Percent effectiveness of Exzolt Cattle-CA1 was 100% in Groups A, B, C, and D up to 77 days. Rain exposure as early as 6 hr post-treatment did not affect the therapeutic or persistent effectiveness of Exzolt Cattle-CA1 in beef cattle.

HOW SUPPLIED: Exzolt Cattle-CA1 is available in 250 mL, 1L, and 5L bottles.

STORAGE AND HANDLING: Store at or below 30°C (86°F), with excursions to 40°C (104°F). **Use within 6 months after first opening.** Store the dosing applicator when loaded with product at or below 30°C (86°F) and use within 1 week.

Distributed by: Intervet Inc., (d/b/a Merck Animal Health), Rahway, NJ 07065

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