

Exzolt® Cattle-CA1 (fluralaner topical solution)

IT'S MORE THAN A BREAKTHROUGH.

EXZOLT® CATTLE-CA1
(fluralaner topical solution)
is a first-of-its-kind
FDA conditionally approved
pour-on for New World
screwworm and cattle fever tick.

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EXZOLT® CATTLE-CA1 (fluralaner topical solution)

Frequently Asked Questions

1. 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.

2. 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.

3. 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.



4. 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.

5. Is there research on fluralaner in cattle?

Backed by over 170 global clinical research studies, fluralaner has demonstrated safety and efficacy across species.

Fluralaner products, which include Bravecto® (fluralaner) Chews, Bravecto® (fluralaner for extended-release injectable suspension) Quantum, Bravecto® Topical (fluralaner topical solution) and Bravecto® 1-Month (fluralaner), are approved in 93 markets with over 270 million doses distributed worldwide across species.

The first countries with approvals for use of fluralaner in cattle are Brazil, Mexico and Australia.

Adverse events for fluralaner are rare, based on global reporting.

(Continued inside)

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6. How do you administer EXZOLT CATTLE-CA1?

Administer as a pour-on at 1 mL per 44 lbs of body weight, applied along the dorsal midline from withers to the base of the 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.

7. When should EXZOLT CATTLE-CA1 be administered?

Product use should be discussed with your veterinarian. This product is only available as a prescription from your veterinarian.

New World screwworm:

- Treatment: Apply 1 dose for active infestations.
- Prevention: Use immediately at wound creation (e.g., castration, dehorning).

Cattle fever tick:

- Treatment & Control: Apply to new arrivals under your veterinarian's guidance.

8. How does it work?

Fluralaner targets the nervous systems of these parasites, effectively killing them and protecting cattle from infestation.

9. What precautions should be taken when administering to cattle?

Wear protective gloves, long sleeve shirt, pants and avoid skin and eye exposure during handling. This product can be flammable. Keep the product away from extreme heat or open flame, including branding irons.

10. 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.

11. 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.

12. Will parasites develop resistance to EXZOLT CATTLE-CA1?

Currently, no resistance is known. A comprehensive parasite control strategy helps delay resistance.

13. How should I store the product?

Store in original packaging at room temperature (59–86°F), away from sunlight, children and pets. After opening, use within 6 months.

14. Does it control horn files?

EXZOLT CATTLE CA-1 is only approved for treatment and control of cattle fever tick and treatment and prevention of New World screwworm myiasis. Off-label or extra-label use is prohibited by federal law for conditionally approved products.

15. Can I use on wildlife, goats and sheep?

EXZOLT CATTLE CA-1 is only approved for use in cattle. Off-label or extra-label use is prohibited by federal law for conditionally approved products.

16. Does it control lice?

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17. Can I use in breeding bulls?

EXZOLT CATTLE CA-1 is not approved for use in bulls intended for breeding over 1 year of age, as reproductive safety has not been evaluated.

18. What personal protective equipment (PPE) should be used when handling or applying the product?

Personal protective equipment should be worn, such as gloves, long sleeve shirt and pants, as well as glasses or goggles, while handling the product.

19. How quickly should I use the product after opening the container?

Use within 6 months after first opening.

IMPORTANT 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.

20. Can I give to calves younger than 2 months of age?

The product has not been tested for use with calves younger than 2 months of age.

21. Will it work for other ticks in the US?

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