Fact Sheet: Emergency Use Authorization of CLiK Extra (dicyclanil topical suspension) Wound Spray for New World Screwworm (NWS)

Emergency Use Authorization Spanish Translation: www.clik-extra-nws.com/spanish
Autorización de Uso de Emergencia traducción al español: www.clik-extra-nws.com/spanish

CLiK Extra (dicyclanil topical suspension) wound spray contains 65 mg/mL of dicyclanil. CLiK Extra is an insect growth regulator, which is a type of ectoparasiticide.

Original EUA Authorized Date: 08/07/2026

Emergency Use Authorization of CLiK Extra (dicyclanil topical suspension) Wound Spray for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product CLiK Extra (dicyclanil topical suspension) wound spray for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured[1] wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn. CLiK Extra is not approved for this use.

Limitations of Authorized Use

It is a violation of Federal law to use this drug product other than as directed in this fact sheet.

Sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep must not be slaughtered or harvested for human consumption within 86 days of treatment.

For captured cervids, captured American bison, and captured bighorn sheep, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 86 days of treatment.

Treated Sonoran pronghorn and camelids may not be used for human consumption.

A milk discard time has not been established for this product. Do not use in animals producing milk for human consumption.

A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

CLiK Extra (dicyclanil topical suspension) wound spray is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CLiK Extra (dicyclanil topical suspension) wound spray under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Product Description

[1] Definitions for “captive wildlife” and “captured wildlife” can be found in the last section of the USDA APHIS New World Screwworm Response Playbook, accessible at https://www.aphis.usda.gov/animal-emergencies/nws

CLiK Extra (dicyclanil topical suspension) wound spray is a pink liquid. Each mL of CLiK Extra contains 65 mg dicyclanil, 200 mg propylene glycol, 100 mg medium-chain triglycerides, 20 mg distilled monoglycerides, 3.00 mg propyl parahydroxybenzoate, 2.50 mg polysorbate, 1.50 mg methyl parahydroxybenzoate (E218), 0.80 mg carbomer copolymer, 0.50 mg disodium edetate, 0.50 mg butylates hydroxytoluene, 0.05 mg ponceau 4R, sodium hydroxide, and purified water.

Directions

For external use only. Shake well before use. Clean the wound(s) prior to drug application. Apply on or around wound(s) using a Fan-Spray 10 mL topical applicator by Simcro Datamars. Use disposable gloves during application and wash hands thoroughly after use.

Use the following dosing table for maximum volume per animal based on body weight. If there are multiple wounds on a single animal, divide the total volume across all wounds as necessary. Small wounds may not need the total volume.

Bodyweight (kg)	Total volume/animal (mL)
10 – 20	Up to 20
21 – 30	Up to 24
31 – 50	Up to 30
> 50	Up to 36

Where possible, treated animals should be kept out of rain and away from waterways for at least one hour after treatment.

CLiK Extra will not treat an active NWS infestation. This drug is for prevention of NWS myiasis only. For prevention of myiasis associated with wounds, birth, and following surgical/husbandry procedures (e.g., dehorning, ear tagging, castration, tail docking, shearing), apply at the time of wound appearance/creation. If a wound is already infested, or an infestation develops after CLiK Extra administration, alternative treatment is necessary.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of NWS. Consult your veterinarian for appropriate wound care when CLiK Extra is administered to prevent myiasis.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from foreign approvals, dose determination studies, a margin of safety study, and scientific literature, it is reasonable to believe that CLiK Extra (dicyclanil topical suspension) wound spray may be effective for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, and when used under the conditions described in this authorization, the known and potential benefits of CLiK Extra (dicyclanil topical suspension) wound spray outweigh the known and potential risks.

In sheep, one study conducted in Uruguay in 2012 to 2013 used the 50 mg/mL (5%) concentration of dicyclanil topical suspension in lambs. A treated group and an untreated control group contained 15 lambs each. All lambs were tail docked and the treated lambs had dicyclanil topical suspension applied directly to the tail docking site at a volume of 20 mL each. All lambs

were evaluated twice daily for 18 days for myiasis via natural infestation. No treated animals were reported with myiasis. By Day 13, 8 out of 15 control animals had myiasis. This study demonstrated dicyclanil topical suspension may be effective in preventing NWS myiasis in sheep.

Other available data in sheep are from the Australia and New Zealand registration dossiers, that include multiple dose determination studies and several large field studies demonstrating effectiveness against various blowfly species (e.g., *Lucilia sericata, L. cuprina*, and *Wohlfahrtia magnifica*) to support the prevention of blowfly strike indication. Although this information does not provide effectiveness data for NWS, these large studies demonstrate the safe use of 65 mg/mL (6.5%) concentration of dicyclanil topical suspension in sheep across the United Kingdom (data included in the Australian dossier), Australia, and New Zealand and in a wide range of sheep age, breed, body weight, and wool length. Adverse event reports were typical of issues common to sheep husbandry and were reported at similar rates across both treated and control groups across studies.

One margin of safety study in sheep (from the New Zealand dossier) conducted in Switzerland in 1996 evaluated the safety of dicyclanil topical suspension at the 50 mg/mL concentration. There were 8 sheep in each dose group and they were 3 months of age. Animals were randomly assigned to a negative control group or one of the following treated dose groups: 1X, 3X, or 10X, corresponding to 25 mL, 75 mL, and 250 mL dicyclanil topical suspension, respectively, for lambs weighing between 21 and 30 kg; and 30 mL, 90 mL, and 300 mL, respectively, for lambs weighing between 31 and 50 kg. The average dose in the 10X group equated to a 461 mg/kg dose of dicyclanil topical suspension. On Days 1, 8, and 15, the lambs received a single spray of dicyclanil topical suspension down the topline and around the breech. Necropsies occurred on Days 20 and 21. Parameters measured included regular general health observations, treatment day observations, physical examinations, feed intake, wool length, body weights, clinical pathology, gross necropsy, and histopathology. No adverse events related to the test article were reported.

Four studies were evaluated to support the effectiveness of dicyclanil topical suspension in cattle against NWS. Two dose determination studies were conducted in 2016 in Brazil using the 50 mg/mL concentration. In the first study, dicyclanil topical suspension was administered to animals in groups receiving various volumes applied to circular wounds created surgically on the neck and rump. There were 10 animals in each group. Animals were then continuously exposed to natural NWS infestations. None of the 10 animals that received 20 mL of dicyclanil topical suspension had myiasis up to and including Day 10. In the second dose determination study, following surgical castration, dicyclanil topical suspension was applied to the surgical site in 15 animals. On Day 8, 1 of the 15 animals that received 16 mL of dicyclanil topical suspension had myiasis. Both studies demonstrated dicyclanil topical suspension may be effective in preventing NWS myiasis in cattle.

The third study conducted in Uruguay in 2012 to 2013 used the 50 mg/mL concentration of dicyclanil topical suspension on 2-month-old calves following surgical castration. Animals were then exposed to natural NWS infestation and evaluated twice daily for 15 days. Seven calves received a total volume of 30 mL (15 mL in scrotal sac, 15 mL in periscrotal area) and 6 animals were untreated controls. While none of the treated animals were observed with myiasis during the study, only one control animal had myiasis, therefore indicating natural infestation pressure was not strong in this trial.

The fourth study was conducted in 1996 in Argentina in cattle five to six months of age. Twenty animals received 20 mL of 50 mg/mL dicyclanil topical suspension after surgical castration and twenty animals were untreated controls. After castration, all animals were exposed to natural NWS infestation. Animals were evaluated for 25 days. By the end of the study, 1 treated animal had myiasis on Day 19 compared to 16 out of the 20 control animals that had myiasis. These two papers demonstrated dicyclanil topical suspension may be effective in preventing NWS myiasis in cattle.

Although the available effectiveness data for dicyclanil topical suspension in sheep and cattle against NWS was conducted using the 50 mg/mL concentration and not the 65 mg/mL concentration, it was concluded the difference in concentration would not be expected to negatively impact the effectiveness of 65 mg/mL dicyclanil topical suspension, because at least the same level of effectiveness would be expected from a higher dosage of a topical drug applied directly to the wound.

There is no further safety data available in cattle. However, no adverse events were reported in the four effectiveness studies described previously.

Further pharmacokinetic and toxicological information on dicyclanil topical suspension was available from an EMA Dicyclanil Summary Report, dated 1999 (European Agency for the Evaluation of Medicinal Products, Veterinary Medicines Evaluation Unit). This report stated less than 5% of dicyclanil was systemically absorbed when applied to sheep. Additionally, toxicologic studies were summarized and reported the acute LD50 (median lethal dose) in rats by oral route was 520 mg/kg. The acute LD50 in rats by dermal route was reported as greater than 2000 mg/kg. This information supports that this drug has poor systemic absorption. Given the highest mg/kg dose an animal would receive is 130 mg/kg based on body weight and the dosing table provided under this authorization, this information supports the safety of dicyclanil topical suspension when applied topically in non-wooled animals.

There is no available effectiveness or safety data on the use of dicyclanil topical suspension on goats, swine, camelids, cervids, American bison, bighorn sheep, and Sonoran pronghorn. However, due to the low systemic absorption of this drug, its topical application and local action on a wound, and the toxicological evidence that demonstrated relatively high LD50 values in rats via both oral and dermal routes, it is reasonable to believe this drug, when applied topically around or on a wound in these species, may be effective in preventing NWS infestation. Additionally, for the ruminant species in this indication, it was concluded that the field data in sheep could provide extrapolated support of safety in other ruminant species in a drug that has limited systemic absorption.

FDA evaluated relevant human food safety information and concluded that the food products obtained from treated animals are safe for human consumption when the conditions of use granted by the EUA are followed, including the withdrawal period listed below.

WARNINGS

Withdrawal Periods and Residue Warnings:

Sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep must not be slaughtered or harvested for human consumption within 86 days of treatment. For captured cervids, captured American bison, and captured bighorn sheep, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 86 days of treatment. Treated Sonoran pronghorn and camelids may not be used for human consumption. A milk discard time has not been established for this product. Do not use in animals producing milk for human consumption. A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

User Safety Warnings

Not for use in humans. Keep out of reach of children.

Wash hands after use.

In case of accidental ingestion, do not induce vomiting. Seek medical advice immediately and show the Fact Sheet or the label to the physician.

Contact with skin and eyes should be avoided. Redness and irritation may develop after skin or eye contact. Use disposable gloves and protective clothing when handling this product and wash hands after use.

In case of skin contact, remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water.

In case of accidental eye exposure:

- Wash the eyes with water for at least 15 minutes.
- If wearing contact lenses, rinse the eyes first, then remove contacts and continue to rinse with water.
- If redness and swelling occur, seek medical advice immediately and show the Fact Sheet or label to the physician.

Do not eat, drink, or smoke while using this product.

Residues remain on fleece and fiber for up to three months after treatment. Wear gloves when handling treated area(s) on the animal, and do not shear treated animals during that time.

To obtain a Safety Data Sheet (SDS), contact Elanco Product & Veterinary Support at 1-800-428-4441 or visit https://www.elanco.com/us/elanco-safety-data-sheets.

Environmental Warnings

Treated animals should be kept away from surface waters for at least one hour after treatment. There is a serious risk to aquatic life if this advice is not followed. Dicyclanil may adversely affect aquatic organisms. Do not permit water runoff from feed lots to enter lakes, streams or ponds. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Reporting Side Effects

Reporting of side effects potentially related to CLiK Extra use under this EUA is strongly encouraged.

Report side effects, lack of effectiveness, and product defects using any of these methods:

1. Contact Elanco Animal Health at 1-800-428-4441,
2. Download and submit Form FDA 1932a available at https://www.fda.gov/reportanimalae, or
3. Contact FDA at 1-888-FDA-VETS to request this form.

When reporting side effects on Form FDA 1932a, provide the following information when available:

- Age, species and breed, sex, and weight of animal(s)
- Overall health status, number of animals treated, and number of animals affected
- Write “CLiK Extra use for NWS under an EUA” in the section labeled “**Adverse Event/Product Problem/Product Use Error**.”
- Describe the signs you observed, when they started in relation to the medication, how long they lasted, any treatment given by you or your veterinarian, and whether/when the animal(s) recovered.
- Note any pre-existing health problems of the animal(s) and any other medications or treatments they are currently receiving.
- Provide details about the use of the product, including dose given, the route of administration, and lot number.

Contact Information

For technical assistance, contact Elanco Animal Health at 888-545-5973 or https://www.elanco.com/us/contact.

Justification for Emergency Use of Animal Drugs for NWS

The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*); and

- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[2]

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances declared by the Secretary of HHS to justify emergency use authorization, including, among others, a determination that there is a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[3]

Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;

- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:

    - the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and

    - the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

- There is no adequate, approved,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

How Supplied

0.8 L and 2.2 L bottles

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[2] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

[4] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.

[5] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Dispensing Status

Over the counter (OTC)

Storage Conditions

Store at or below 86°F (30°C). Do not freeze. Protect from light. Store in original container tightly closed in a dry, cool place.

Manufactured for:
Elanco US Inc.
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Indianapolis, IN 46221

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