Fact Sheet for Veterinarians: Emergency Use Authorization of Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) for New World Screwworm (NWS)

Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) is an oral parasiticide for use in dogs and puppies. The recommended minimum dose is 0.54 mg/lb (1.2 mg/kg) sarolaner, 0.011 mg/lb (24 µg/kg) moxidectin, and 2.27 mg/lb (5 mg/kg) pyrantel (as pamoate salt). Simparica TRIO is available in six flavored tablet sizes.

Original EUA Authorized Date: 08/13/2026

Emergency Use Authorization of Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the approved product Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. Simparica TRIO is not approved for this use.

Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) (NADA 141-521) is approved for other uses in dogs and puppies.[1]

Limitations of Authorized Use

Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) 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.

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

[1] Simparica TRIO is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and hookworm (L4, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*) infections. Simparica TRIO kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the prevention of *Dipylidium caninum* (tapeworm) infections as a direct result of killing *Ctenocephalides felis* vector fleas on the treated dog, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick) for one month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater. Simparica TRIO is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

- 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]

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

Product Description

Refer to the Simparica TRIO package insert for full **Product Description** information.

Dosage and Administration

Simparica TRIO is given orally at the recommended minimum dose of 0.54 mg/lb (1.2 mg/kg) sarolaner, 0.011 mg/lb (24 µg/kg) moxidectin, and 2.27 mg/lb (5 mg/kg) pyrantel (as pamoate salt).

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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

Dosing Schedule

Body Weight (lbs)	Sarolaner per Tablet (mg)	Moxidectin per Tablet (mg)	Pyrantel per Tablet (mg)	Number of Tablets Administered
2.8 to 5.5	3	0.06	12.5	One
5.6 to 11	6	0.12	25	One
11.1 to 22	12	0.24	50	One
22.1 to 44	24	0.48	100	One
44.1 to 88	48	0.96	200	One
88.1 to 132	72	1.44	300	One
>132	Administer the appropriate combination of tablets			

Risk-Benefit Consideration for Dogs on Other Antiparasitic Products:

The isoxazoline drug class carries a known risk of neurologic adverse reactions, including tremors, ataxia, and seizures, that have been reported even in dogs with no prior seizure history. If a dog is currently receiving another antiparasitic product, especially another combination product containing an active ingredient from the isoxazoline and/or macrocyclic lactone drug class, for routine ecto- and endoparasite control, veterinarians should consider administering Simparica TRIO to dogs diagnosed with NWS larvae based on a risk-benefit assessment and the emergency nature of the treatment of the NWS infestation.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from a laboratory effectiveness study, it is reasonable to believe that Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) may be effective for the treatment of NWS myiasis in dogs and puppies, and when used under the conditions described in this authorization, the known and potential benefits of Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) outweigh the known and potential risks.

Title:
Assessment of Efficacy of Antiparasitic Product Composed of Sarolaner, Moxidectin and Pyrantel (as pamoate salt) in the Treatment of Myiasis caused by *Cochliomyia hominivorax* larvae in Experimentally Infested Dogs. (Study No. A162R-BR-25-F08)

Study Design:
The study was conducted in Brazil in 2025. Twelve healthy dogs (9.9 to 18.3 kg, 24 to 107 months old) were enrolled. On Day -2, under local and general anesthesia, each dog received a 2 cm surgical wound on the neck. On Day -1, the wounds were infested with approximately 50

C. hominivorax first instar (L1) larvae. On Day 0, dogs were allocated into two groups and either treated with Simparica TRIO or food pellets (control).

Drug administration was on Day 0. Dogs were fasted for at least 12 hours before treatment and remained without food for approximately 3 additional hours after treatment. Dogs in the treated group received a combination of tablets to deliver a sarolaner dose as close to 1.2 mg/kg, without underdosing. The sarolaner doses ranged from 1.2 to 1.4 mg/kg. Dogs in the control group underwent the same procedures but were offered a food pellet.

On Day 0, every 15 minutes for the first hour, every hour at 2 through 6 hours, and at 12 and 24 hours after treatment, *C. hominivorax* larvae expelled from the wound into the cage trays were counted, categorized as live or dead, and classified according to instar. On Day 1 (24 hours post-treatment), dogs were anesthetized and the remaining *C. hominivorax* larvae were manually recovered from the wound, counted, categorized as live or dead, and classified according to instar. The wounds were cleaned and treated with an antibiotic ointment.

Results:

1. Expelled Live and Dead Larvae Counts:
   Overall, the dogs in the control group expelled fewer live and dead larvae than the dogs in the treated group during the 24-hour study. All of the expelled larvae (both live and dead) from the Simparica TRIO group were second instar larvae. Expelled larvae (both live and dead) from the control group were second or third instar larvae.

   Table 1: Expelled Live and Dead Mean Larval Counts

Treatment Group	Arithmetic Mean Live Larval Count	Arithmetic Mean Dead Larval Count
Control	2.5	0.33
Simparica TRIO	12.2	1.8

2. Recovered Larvae on Day 1:
   All 6 control dogs and 3 out of 6 treated dogs had recovered larvae on Day 1. In the control group, no dead larvae were recovered and the number of live, recovered larvae ranged from 6 to 54 (arithmetic mean = 30.7). In the treated group, no live larvae were recovered and the number of dead, recovered larvae ranged from 0 to 13 (arithmetic mean = 2.5). The percent effectiveness of Simparica TRIO, based on the absence of live, recovered larval counts on Day 1, compared to the control group, was 100%.

   All recovered larvae in the control group were third instar. In the treated group, all recovered larvae were second instar except for one (dead) third-instar larva.

3. Additional Parameters:
   The larval expulsion rate (number of live and dead expelled larvae/total number of larvae (expelled and recovered) x 100) and average larvicidal effectiveness (number of dead (expelled and removed) larvae/total number of larvae (expelled and recovered)) were both higher in treated dogs compared to control dogs.

Table 2: Larval Expulsion Rate and Larvicidal Effectiveness

Treatment Group	Larval Expulsion Rate (% (range))	Larvicidal Effectiveness (% (range))
Control	8.5% (0-16.7%)	1.0% (0-16.7%)
Simparica TRIO	84.8% (38.1-100%)	26.3% (3.3-61.9%)

Adverse Reactions:
One treated dog vomited food 3 hours after Simparica TRIO administration.

Conclusions:
The results of the study demonstrate that Simparica TRIO may be effective for the treatment of infestations caused by New World screwworm (*C. hominivorax*) in dogs and puppies. The primary mechanism of action against *C. hominivorax* appears to be live larval expulsion. Vomiting should be considered a drug-related adverse reaction.

User Safety Warnings

Not for use in humans. Keep this and all drugs out of reach of children.

To obtain a Safety Data Sheet (SDS), contact Zoetis Inc. at 1-888-963-8471.

Animal Safety Warnings and Precautions

Sarolaner, one of the ingredients in Simparica TRIO, is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.

The safe use of Simparica TRIO has not been evaluated in breeding, pregnant, or lactating dogs.

The safety and effectiveness of Simparica TRIO has not been tested in puppies less than 8 weeks of age or weighing less than 2.8 lbs (1.3 kg).

Effective treatment of NWS myiasis includes removal of the larvae. Appropriate wound care, including surgical debridement as needed and pain management, should be implemented.[6]

Refer to the Simparica TRIO package insert for full **Precautions** information.

Adverse Reactions

Refer to the Simparica TRIO package insert for full prescribing information, including **Animal Safety**, **Adverse Reactions**, and **Post-Approval Experience**.

[6] Cutolo, A. A., Perier, N., Menz, I., Thyssen, P., Silva, F. O., & Beugnet, F. (2021). Efficacy of afoxolaner (NexGard®) on the treatment of myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Veterinary parasitology, regional studies and reports*, *24*, 100569.

As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) use under this EUA by:

(1) contacting Zoetis Inc. at 1-888-963-8471,

(2) downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or

(3) contacting FDA at 1-888-FDA-VETS to request this form.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- The statement "Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) use for NWS under an EUA" under the **"Adverse Event/Product Problem/Product Use Error"** heading
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes)
- Patient's pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, lot number)

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- An event that causes an abortion, stillbirth, or infertility
- A congenital anomaly or birth defect in offspring of treated animals
- A prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions)
- An event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability)

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the mechanisms and including the information identified above for **SERIOUS ADVERSE EVENTS**.

Additional Information for Veterinarians

Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. Fact Sheets will be made available to veterinarians.

Veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs co-administered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

Veterinary facilities will maintain any health records for the authorized use in the Letter of Authorization for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Zoetis Inc., HHS, and FDA for inspection upon request.

Information for Client (e.g., Animal Owner or Caretaker)

The lifecycle for *C. hominivorax* is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. Dogs may become reinfested following treatment.

Clients should be advised that:

- Gloves should be worn if cleaning the wound, or the dog's bedding, or disposing of larvae.
- Dogs should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live larvae may exit the wound and be deposited on bedding or areas where the dog sits or lies after treatment.
- If expelled larvae are seen, owners should place the larvae in a sealed container with rubbing alcohol.
- If there is worsening of the wound, the owner should contact the veterinarian.

Storage Information

Refer to the Simparica TRIO package insert for full **Storage Conditions** information.
Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

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