Fact Sheet: Emergency Use Authorization of Ivomec (ivermectin) Injection for New World Screwworm (NWS)

Ivomec (ivermectin) injection is a parasiticide provided as an injectable solution for subcutaneous administration. This product contains 10 mg/mL of ivermectin.

Original EUA Authorized Date: 02/05/2026

Emergency Use Authorization for Ivomec (ivermectin) Injection 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 Ivomec (ivermectin) injection for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal[1]. Ivomec (ivermectin) injection is not approved or conditionally approved for this use.

Ivomec (ivermectin) injection (NADA 128-409) is approved for other uses in cattle, swine, reindeer, and American bison. Please refer to the Ivomec (ivermectin) injection package insert for the currently approved indications.

Limitations of Authorized Use

Ivomec (ivermectin) injection is not authorized for use in female dairy cattle producing milk for human consumption and calves that will be processed for veal.

Ivomec (ivermectin) injection is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Ivomec (ivermectin) injection 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 authorization revoked sooner.

Product Description

Refer to the Ivomec (ivermectin) injection package insert for full **Product Description** information.

Directions

Refer to the Ivomec (ivermectin) injection package insert for full **Dosage and Administration** information specific for cattle.

For the prevention of infestations caused by NWS in newborn calves, administer Ivomec injection within 24 hours of birth. For the prevention of scrotal myiasis, administer Ivomec injection at the time of castration. For the prevention of wound myiasis, administer Ivomec injection at the time of wound appearance. Monitor the wound for signs of myiasis. If a wound is already infested, or if an infestation develops after Ivomec administration, alternative treatment is necessary. Ivomec is not authorized for the treatment of infestations of NWS.

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[1] Hereinafter, “cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal” will be referred to as "certain cattle."

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Information Supporting Emergency Use Authorization

Based on the scientific evidence available to FDA, including summaries of dose confirmation studies and published scientific literature, it is reasonable to believe that Ivomec (ivermectin) injection may be effective for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle, and when used under the conditions described in the authorization, the known and potential benefits of Ivomec (ivermectin) injection outweigh the known and potential risks.

Four dose confirmation studies conducted in Brazil and Argentina in 1991 and 1992 evaluated the effectiveness of Ivomec (ivermectin) injection for the prevention of infestations caused by NWS larvae (myiasis) in cattle. These studies included beef calves of various breeds treated subcutaneously with a single dose of 200 mcg ivermectin/kg body weight (BW), immediately following castration or within 24 hours of birth, and untreated control calves. Calves were housed on pastures where they were exposed to natural infestations of NWS. No myiasis requiring rescue treatment developed in the first week after castration or birth in the calves treated with Ivomec (ivermectin) injection, while myiasis was observed in 30% to 90% of the untreated control calves.

Studies published in the scientific literature evaluated the effectiveness of a single subcutaneous dose of 200 mcg ivermectin/kg BW for the prevention of infestations caused by NWS larvae (myiasis) in cattle.

- Twelve studies conducted in Argentina and Brazil in the 1990s, reported that Ivomec (ivermectin) injection given in the first 24 hours after birth, at the time of creation of an artificial wound, or at the time of castration, prevented myiasis in over 97% of the calves exposed to natural infestations of NWS[2,3].

- A study conducted during the rainy season in Brazil in 2019 reported that the effectiveness of Ivomec (ivermectin) injection for prevention of naval myiasis when given on the day of birth was 28.5% on Day 3, and 13.5% on Day 7, when compared to the control group[4].

There are several limitations of the data supporting the benefits of Ivomec (ivermectin) injection for the prevention of infestations caused by NWS myiasis in cattle. All the studies were conducted in Argentina and Brazil and, except for one study, were conducted prior to 2000. The susceptibility of current field isolates of NWS larvae to treatment with Ivomec (ivermectin) injection may differ due to the widespread use of ivermectin and other macrocyclic lactones for

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[2] Anziani, O. S., & Loreficce, C. (1993). Prevention of cutaneous myiasis caused by screw worm larvae (*Cochliomyia hominivorax*) using ivermectin. *Zentralbl Veterinarmed B*, *40*(4), 287-290.
[3] Benitez Usher, C., Cruz, J., Carvalho, L., Bridi, A., Farrington, D., Barrick, R. A., & Eagleson, J. (1997). Prophylactic use of ivermectin against cattle myiasis caused by *Cochliomyia hominivorax* (Coquerel, 1858). *Vet Parasitol*, *72*(2), 215-220.
[4] de Aquino, L. M., Ferreira, L. L., Zapa, D. M. B., Heller, L. M., Trindade, A. S. N., de Morais, I. M. L., Salvador, V. F., Leal, L., Couto, L. F. M., de Mendonça, R. P., Costa, I. S., Soares, V. E., de Oliveira Monteiro, C. M., & Lopes, W. D. Z. (2022). Number of rainy days in a week influencing screwworm navel myiasis in beef calves and efficacies of injectable and topical antiparasitics. *Res Vet Sci*, *152*, 698-706.

the treatment of various internal and external parasites in cattle. Differences in the level of preventative effectiveness between studies may be the result of various factors including, but not limited to, larval susceptibility, antiparasitic resistance, wound factors, infestation pressure, and pharmacokinetic factors. The effectiveness of Ivomec (ivermectin) injection for the prevention of NWS infestations should be closely monitored.

The dose confirmation studies and published literature support the potential benefit of Ivomec (ivermectin) injection in certain cattle for the prevention of infestations caused by NWS myiasis. The animal safety profile for cattle, including male and female reproducing cattle, is well-characterized, and the information provided support that the food products obtained from the treated animals are safe for human consumption when used under the conditions described in the authorization. Consultation with a veterinarian for assistance with the overall management of parasitism, including NWS larvae (myiasis), should mitigate risks associated with effectiveness limitations and antiparasitic resistance.

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 and milk discard time listed below.

WARNINGS

Withdrawal Periods and Residue Warnings: Cattle must not be slaughtered for human consumption within 35 days of treatment. Because a milk discard time has not been established for this product, do not use in female dairy cattle 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.

To obtain a Safety Data Sheet(s), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251.

Precautions

Refer to the Ivomec (ivermectin) injection package insert for full **Precautions** information.

Other Warnings

Widespread use of any antiparasitic product to prevent NWS myiasis could encourage the development of parasite resistance. When using Ivomec (ivermectin) injection for the prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound, a veterinarian should be consulted for management of the overall parasite program in treated cattle, including the treatment and control of other internal and external parasites.

Refer to the Ivomec (ivermectin) injection package insert for full **Other Warnings** information related to antiparasitic resistance.

Environmental Warning

Refer to the Ivomec (ivermectin) injection package insert for full **Environmental Safety** information.

Reporting Side Effects

Reporting of side effects potentially related to Ivomec (ivermectin) injection use under this EUA is strongly encouraged.

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

1. Contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251, or
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 “Ivomec 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.

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[5].

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.[6]

Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the 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, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[7]

Dispensing Status

Over the counter (OTC)

Storage Conditions

Refer to the package insert for full **Storage Conditions** information.

Marketed by:
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

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[5] 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
[6] 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
[7] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization