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

Rev. 02/2026

[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

ivomec® (ivermectin) Injection for Cattle and Swine

Approved by FDA under NADA # 128-409 160026 | 160027 | 160028 | 160029

1% Sterile Solution

A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine

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

INTRODUCTION

IVOMEC® (ivermectin) is an injectable parasiticide for cattle and swine. One low-volume dose effectively treats and controls the following internal and external parasites that may impair the health of cattle and swine: gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* in cattle), lungworms, grubs, sucking lice, and mange mites of cattle; and gastrointestinal roundworms, lungworms, lice, and mange mites of swine. Discovered and developed by scientists from Merck Research Laboratories, ivermectin is a novel chemical entity. Its convenience, broad-spectrum efficacy, and safety margin make IVOMEC Injection a unique product for parasite control of cattle and swine.

PRODUCT DESCRIPTION

Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents isolated from fermentation of *Streptomyces avermitilis*.

IVOMEC Injection is a clear, ready-to-use, sterile solution containing 1% ivermectin, 40% glycerol formal, and propylene glycol, q.s. ad 100%. IVOMEC Injection is formulated to deliver the recommended dose level of 200 mcg ivermectin/kilogram of body weight in cattle when given subcutaneously at the rate of 1 mL/110 lb (50 kg). In Swine, IVOMEC Injection is formulated to deliver the recommended dose level of 300 mcg ivermectin/kilogram body weight when given subcutaneously in the neck at the rate of 1 mL per 75 lb (33 kg).

MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligandgated chloride channels and they do not readily cross the blood-brain barrier.

INDICATIONS

Cattle: IVOMEC Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice, and mange mites in cattle:

Gastrointestinal Roundworms (adults and fourth-stage larvae): *Ostertagia ostertagi* (including inhibited *O. ostertagi*), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Bunostomum phlebotomum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only)
Lungworms (adults and fourth-stage larvae): *Dictyocaulus viviparus*
Cattle Grubs (parasitic stages): *Hypoderma bovis, H. lineatum*
Sucking Lice: *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*
Mites (scabies): *Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*

Persistent Activity

IVOMEC Injection has been proved to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostrongylus axei* and *Cooperia punctata* for 21 days after treatment; *Haemonchus placei* and *Cooperia oncophora* for 14 days after treatment.

Swine: IVOMEC Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites in swine:

Gastrointestinal Roundworms: Large roundworm, *Ascaris suum* (adults and fourth-stage larvae), Red stomach worm, *Hyostrongylus rubidus* (adults and fourth-stage larvae), Nodular worm, *Oesophagostomum* spp. (adults and fourth-stage larvae), Threadworm, *Strongyloides ransomi* (adults)
Somatic Roundworm Larvae: Threadworm, *Strongyloides ransomi* (somatic larvae)
Sows must be treated at least seven days before farrowing to prevent infection in piglets.
Lungworms: *Metastrongylus* spp. (adults)
Lice: *Haematopinus suis*
Mange Mites: *Sarcoptes scabiei* var. *suis*

DOSAGE

Cattle: IVOMEC Injection should be given only by subcutaneous injection under the loose skin in front of or behind the shoulder at the recommended dose level of 200 mcg of ivermectin per kilogram of body weight. Each mL of IVOMEC contains 10 mg of ivermectin, sufficient to treat 110 lb (50 kg) of body weight (maximum 10 mL per injection site).

Body Weight (lb)	Dose Volume (mL)
220	2
330	3
440	4
550	5
660	6
770	7
880	8
990	9
1100	10

Swine: IVOMEC Injection should be given only by subcutaneous injection in the neck of swine at the recommended dose level of 300 mcg of ivermectin per kilogram (2.2 lb) of body weight. Each mL of IVOMEC contains 10 mg of ivermectin, sufficient to treat 75 lb of body weight.

	Body Weight (lb)	Dose Volume (mL)
Growing Pigs	19	1/4
	38	1/2
	75	1
	150	2
Breeding Animals (Sows, Gilts, and Boars)	225	3
	300	4
	375	5
	450	6

Do not underdose. Ensure each animal receives a complete dose based on a current body weight.

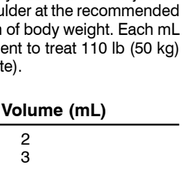
Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

ADMINISTRATION

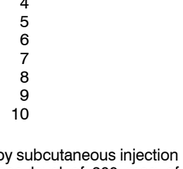
Any single-dose syringe or standard automatic syringe equipment may be used with the 50 mL bottle. Use the 50 mL bottle within 6 months of first puncture and puncture a maximum of 12 times. If more than 12 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16-gauge, discard any product remaining in the bottle immediately after use. When using the 200 mL, 500 mL or 1000 mL pack size, use only automatic syringe equipment. Discard any product remaining in the pack immediately after use.

Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections. The rubber stopper should also be disinfected with alcohol to prevent contamination of the contents. No special handling or protective clothing is necessary.

Cattle: IVOMEC (ivermectin) Injection is to be given subcutaneously only, to reduce risk of potentially fatal clostridial infection of the injection site. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, 1/2 to 3/4" needle is suggested. Inject under the loose skin in front of or behind the shoulder (see illustration).



Swine: IVOMEC® Injection is to be given subcutaneously in the neck. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16- or 18-gauge needle is suggested for sows and boars, while an 18-or 20-gauge needle may be appropriate for young animals. Inject under the skin, immediately behind the ear (see illustration). Mild and transient pain reactions may be seen in some swine following subcutaneous administration.



Recommended Treatment Program

Swine: At the time of initiating any parasite control program, it is important to treat all breeding animals in the herd. After the initial treatment, use IVOMEC Injection regularly as follows:

BREEDING ANIMALS

Sows: Treat prior to farrowing, preferably 7–14 days before, to minimize infection of piglets.

Gilts: Treat 7–14 days prior to breeding.
Treat 7–14 days prior to farrowing.

Boars: Frequency and need for treatments are dependent upon exposure. Treat at least two times a year.

FEEDER PIGS (Weaners/Growers/Finishers)

All weaner/feeder pigs should be treated before placement in clean quarters. Pigs exposed to contaminated soil or pasture may need retreatment if reinfection occurs.

NOTE:

(1) IVOMEC Injection has a persistent drug level sufficient to control mite infestations throughout the egg to adult life cycle. However, since the ivermectin effect is not immediate, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities. Generally, pigs should not be moved to clean quarters or exposed to uninfested pigs for approximately one week after treatment. Sows should be treated at least one week before farrowing to minimize transfer of mites to newborn baby pigs.

(2) Louse eggs are unaffected by IVOMEC Injection and may require up to three weeks to hatch. Louse infestations developing from hatching eggs may require retreatment.

(3) Consult a veterinarian for aid in the diagnosis and control of internal and external parasites of swine.

Special Minor Use

Reindeer: For the treatment and control of warbles (*Oedemagena tarandi*) in reindeer, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under ADMINISTRATION.

American Bison: For the treatment and control of grubs (*Hypoderma bovis*) in American bison, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under ADMINISTRATION.

RESIDUE WARNING: Do not treat reindeer or American bison within 8 weeks (56 days) of slaughter.

WARNING
NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

The Safety Data Sheet (SDS)contains more detailed occupational safety information.To report suspected adverse drug events, for technical assistance, or to obtain a copy of the SDS, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs,contact FDA at 1-888-FDA-VETS, or at www.fda.gov/reportanimalae.

RESIDUE WARNING: Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not treat swine within 18 days of slaughter.

PRECAUTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared without treatment. For cattle, divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction. Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections.

Observe cattle for injection site reactions. Reactions may be due to clostridial infection and should be aggressively treated with appropriate antibiotics. If injection site infections are suspected, consult your veterinarian.

This product is not for intravenous or intramuscular use.

IVOMEC Injection for Cattle and Swine has been developed specifically for use in cattle, swine, reindeer, and American bison **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Restricted Drug (California) - use only as directed.

When to Treat Cattle with Grubs

IVOMEC effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. Destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *Hypoderma lineatum* when it is in the tissue surrounding the esophagus (gullet) may cause salivation and bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with IVOMEC, but can occur with any successful treatment of grubs. Cattle should be treated either before or after these stages of grub development. Consult your veterinarian concerning the proper time for treatment. Cattle treated with IVOMEC after the end of the heel fly season may be retreated with IVOMEC during the winter for internal parasites, mange mites, or sucking lice without danger of grub-related reactions. A planned parasite control program is recommended.

OTHER WARNINGS:

Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.

Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.

Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).

A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Environmental Safety

Studies indicate that when ivermectin comes in contact with soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain 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.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

STORAGE CONDITIONS

Store at or below 25°C (77°F) with excursions permitted up to 30°C (86°F). Protect product from light.

HOW SUPPLIED

IVOMEC Injection for Cattle and Swine is available in four ready-to-use pack sizes:

The 50 mL pack is a multiple-dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 10 head of 550 lb (250 kg) cattle or 100 head of 38 lb (17.3 kg) swine.

The 200 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 40 head of 550 lb (250 kg) cattle or 400 head of 38 lb (17.3 kg) swine.

The 500 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle or 1000 head of 38 lb (17.3 kg) swine.

The 1000 mL is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 200 head of 550 lb (250 kg) cattle or 2000 head of 38 lb (17.3 kg) swine.

Marketed by:
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096
Rev. 08/2023 4033932

Boehringer Ingelheim

Boehringer Ingelheim	Code: 609077-001
GO PAULINIA	SKU #: 160026 | 160027 | 160028 | 160029
INITIALS: JP	Version: D -27/11/2023
Product Component Type Size	Ivomec 1% - INOVAT INSERT
Country(s):	US
Dimensions :	210 x 300 mm
CMO:	INOVAT
Project Number:	LR - 000924
Release:	
Template 95059	Espec. 305-SPEC-022352
CANCEL AND REPLACE:	NEW
Notes:	INOVAT CODE - 4033932

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TECH INFO (not printed)
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U.S. FOOD & DRUG ADMINISTRATION

February 5, 2026

Boehringer Ingelheim Animal Health USA, Inc.
Attention: Tracy Robertson
Regulatory Affairs, Operations
3239 Satellite Blvd.
Duluth, GA 30096

Re: Emergency Use Authorization 006689

Dear Ms. Robertson:

This letter is in response to the request by Boehringer Ingelheim Animal Health USA, Inc. (Boehringer) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Ivomec (ivermectin) injection for 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], pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) 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 New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[2]

Ivomec (ivermectin) injection is an antiparasitic drug that is indicated under NADA 128-409 for the treatment and control of a variety of internal and external parasites in cattle. Ivomec (ivermectin) injection is not approved or conditionally approved for prevention of NWS myiasis.

Based on the scientific evidence available to the FDA, including summaries of dose confirmation studies and published scientific literature, it is reasonable to believe that Ivomec (ivermectin) injection may be effective for 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 in certain cattle, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Ivomec (ivermectin) injection

[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."
[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

outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of Ivomec (ivermectin) injection for 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 in certain cattle, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Ivomec (ivermectin) injection for 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 in certain cattle, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;

2. Based on the scientific evidence available to FDA, it is reasonable to believe that Ivomec (ivermectin) injection may be effective in preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Ivomec (ivermectin) injection when used to prevent NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative[3] to the emergency use of Ivomec (ivermectin) injection for prevention of infestations caused by NWS larvae (myiasis) in certain cattle for the authorized indications.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited as follows:

- Ivomec (ivermectin) injection, as covered by this authorization, will be used only for 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 in certain cattle; and

[3] Other therapeutics are conditionally approved for prevention of infestations caused by NWS larvae (myiasis) in cattle. However, these products are not available alternatives because there are insufficient quantities to meet the demands of a widescale incursion of NWS into the United States. In addition, one conditionally approved product is not an adequate alternative because it requires a prescription, potentially delaying administration. There is a significant benefit to expedient administration of a preventative product, particularly if animals nearby are infested. Thus, FDA concluded that this additional OTC injectable macrocyclic lactone product indicated for prevention of NWS in cattle is needed to meet the demands of a widescale incursion of NWS into the United States.
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

- The use of Ivomec (ivermectin) injection covered by this authorization must be in accordance with the authorized Fact Sheet.

Product Description

Ivomec (ivermectin) injection is derived from the avermectins, a family of broad-spectrum antiparasitic agents. The authorized Ivomec (ivermectin) injection carton label is clearly marked for the approved indications and for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

Store at or below 25°C (77°F) with excursions permitted up to 30°C (86°F). Protect product from light.

Ivomec (ivermectin) injection is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to all users:

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

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of Ivomec (ivermectin) injection, when used for 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 in certain cattle and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the scientific evidence available to FDA, that it is reasonable to believe that Ivomec (ivermectin) injection may be effective for 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 in certain cattle when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Ivomec (ivermectin) injection, as described in this authorization, meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, Ivomec (ivermectin) injection is authorized for 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 in certain cattle as described in this

authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

A. Boehringer will ensure that the authorized Ivomec (ivermectin) injection, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)[5] consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

B. Boehringer will ensure that if a sticker is used on the labeling, that the sticker contains a website address and QR code that link to the authorized Fact Sheet and that the sticker is placed in a blank space or does not obscure any important use or safety information.

C. Boehringer and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

D. Boehringer and authorized distributor(s) will provide to each authorized distributor immediately downstream in the supply chain a copy of this Letter of Authorization and promptly communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

E. Boehringer may request changes to this authorization, including to the authorized Fact Sheet for Ivomec (ivermectin) injection. Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[6]

F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:

   Boehringer will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Boehringer will attempt to determine whether the use of Ivomec (ivermectin) injection was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Boehringer will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

[5] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Boehringer places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[6] Revisions that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, specified cGMPs, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

Submitted reports must state in the "Narrative of Adverse Event" field: "Ivomec use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.

G. Through a process of inventory control, Boehringer and authorized distributor(s) will maintain records regarding distribution of the authorized Ivomec (ivermectin) injection (i.e., lot numbers, quantity, receiving site, receipt date).

H. Boehringer and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination of the declaration or revocation of the authorization, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.

I. Boehringer will comply with all other FD&C Act requirements applicable to the approved product, Ivomec (ivermectin) injection, including, but not limited to, requirements related to registration and listing, drug quality, and manufacturing process, facilities, and equipment in accordance with the approved application[7] unless such requirement is specifically waived or modified for the authorized product in this authorization. Boehringer shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

Conditions of Authorization Related to Advertisements and other Promotional Descriptive Printed Matter

J. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of Ivomec (ivermectin) injection, shall be consistent with the authorized Fact Sheet[8], and the terms set forth in this EUA, as well as comply with FD&C Act section 502(a) and 502(n), and 21 CFR Part 202. Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

K. Boehringer and authorized distributor(s) may not imply that Ivomec (ivermectin) injection is FDA approved or conditionally approved for the authorized use by making statements such as "Ivomec (ivermectin) injection is safe and effective for prevention of infestations caused by NWS (*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". Boehringer and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Ivomec (ivermectin) injection that provide accurate descriptions of safety and

[7] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.
[8] If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of Ivomec (ivermectin) injection shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- Ivomec (ivermectin) injection has not been approved for prevention of infestations caused by NWS (*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;

- Ivomec (ivermectin) injection has been authorized by FDA under an EUA for prevention of infestations caused by NWS (*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

- Ivomec (ivermectin) injection is authorized as described herein 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 FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revised or revoked sooner.

M. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If FDA notifies Boehringer that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Boehringer must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Boehringer to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheet

Electronic Signature Addendum for Submission ID

V-006689-A-0000-OT

Signing Authority (Role)	Letter Date
William Flynn (Center Director) - Acting	2/5/2026

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