Fact Sheet for Veterinarians: Emergency Use Authorization of Ivermectin Liquid for Horses (ivermectin oral solution) for New World Screwworm (NWS)

Ivermectin Liquid for Horses (ivermectin oral solution) is a parasiticide provided as a solution for oral administration. This product contains 10 mg/mL of ivermectin.

Original EUA Authorized Date: 07/15/2026

Emergency Use Authorization of Ivermectin Liquid for Horses (ivermectin oral solution) 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 Ivermectin Liquid for Horses (ivermectin oral solution) for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses. Ivermectin Liquid for Horses is not approved for this use.

Limitations of Authorized Use

Ivermectin Liquid for Horses (ivermectin oral solution) is not authorized for use in species other than horses.

Do not use in horses intended for human consumption.

Ivermectin Liquid for Horses (ivermectin oral solution) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Ivermectin Liquid for Horses (ivermectin oral solution) 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

- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[1]

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

[1] 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

health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[2]

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,[3] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[4]

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

Product Description

Ivermectin Liquid for Horses is a clear, ready-to-use solution. Each mL contains 10 mg of ivermectin.

Dosage and Administration

Ivermectin Liquid for Horses can be administered as an oral drench or by nasogastric intubation. The recommended dose is 91 mcg of ivermectin per pound (200 mcg/kg) of body weight. Each mL contains the recommended dose of ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse. 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.

For the prevention of infestations caused by NWS in newborn foals, administer a single dose of Ivermectin Liquid for Horses to the foal within 24 hours of birth. For the short-term prevention of wound myiasis, administer a single dose of Ivermectin Liquid for Horses at the time of initial wound care. Monitor the wound for signs of myiasis. If a wound is already infested, or if an infestation develops after Ivermectin Liquid for Horses administration, alternative treatment is necessary. Ivermectin Liquid for Horses is not authorized for the treatment of infestations of NWS.

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[2] 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)
[3] "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.
[4] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Ivermectin Liquid for Horses (ivermectin oral solution) may only be effective at preventing NWS myiasis when exposure to NWS flies occurs near the time of administration, since preventative effectiveness may not extend beyond 24 hours after administration. In most cases, additional preventative actions may be necessary to cover the full anticipated healing time of most wounds (e.g., other fly control methods, barrier methods such as bandaging, repellants, etc.).

Multiple dose bottle: Screw the draw-off cap onto the bottle. Insert any standard luer lock or luer slip syringe into the opening of the draw-off cap. Invert the bottle and draw up the calculated dose. Turn the bottle upright and disconnect the syringe. The syringe should not remain inserted in the cap when not in use. Wear gloves to remove the draw-off cap after each use and replace the shipping cap to close the container.

Single dose syringe: Each marking on the syringe plunger will deliver sufficient liquid to treat 110 lb (50 kg) of body weight. Turn the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight marking. Remove the plastic cap from the tip of the nozzle.

For oral administration, clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose on the back of the tongue. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure, do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to ensure the dose is retained.

For administration by nasogastric intubation (gravity or positive flow), use tepid water to flush any remaining drug in the tube into the horse's stomach.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including pharmacokinetic data from a bioequivalence study and information in published scientific literature, it is reasonable to believe that Ivermectin Liquid for Horses (ivermectin oral solution) may be effective for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses, and when used under the conditions described in this authorization, the known and potential benefits of Ivermectin Liquid for Horses (ivermectin oral solution) outweigh the known and potential risks.

There is no clinical data in horses to support the effectiveness of Ivermectin Liquid for Horses (ivermectin oral solution) for the prevention of NWS myiasis. Information to support that Ivermectin Liquid for Horses may be effective in horses is based on clinical studies using ivermectin injection in cattle, the pharmacokinetics (PK) of ivermectin injection in cattle, and the PK of Ivermectin Liquid for Horses in horses, along with other known information about the fly life cycle.

Studies in cattle administered ivermectin injection evaluated the effectiveness of a single subcutaneous dose of 200 mcg ivermectin/kg body weight for the prevention of infestations caused by NWS larvae (myiasis) in cattle.

- Twelve studies conducted in Argentina and Brazil in the 1990s reported that 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.

- A study conducted during the rainy season in Brazil in 2019 reported that the effectiveness of ivermectin injection for prevention of navel 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.

Specific plasma levels of ivermectin necessary to prevent NWS myiasis are unknown. However, FDA compared the PK of ivermectin injection administered subcutaneously in cattle to the PK of Ivermectin Liquid for Horses (ivermectin oral solution) administered orally to horses.

The PK of Ivermectin Liquid for Horses (ivermectin oral solution) was established in a bioequivalence study involving 20 horses treated with a 200 mcg/kg oral dose. When compared to ivermectin injection administered subcutaneously to cattle, the maximum concentration of ivermectin in the blood of horses following oral administration of Ivermectin Liquid for Horses was similar, although in horses the maximum concentration tended to be reached more quickly. However, the decline in blood-level concentrations of ivermectin also occurred much more quickly in horses, suggesting that the duration of effect may be much shorter in horses than in cattle. Considering the PK profile of Ivermectin Liquid for Horses, the results of studies evaluating ivermectin against NWS, and the lifecycle of NWS, the duration of effect is estimated to be approximately 24 hours after administration in horses.

Estimates were based on mean PK parameters and may not reflect individual animal variables and differing environmental conditions.

Based on the totality of information available, Ivermectin Liquid for Horses (ivermectin oral solution) may only be effective at preventing NWS myiasis when exposure to NWS flies occurs near the time of administration, since preventive effectiveness may not extend beyond 24 hours after administration. In most cases, additional preventative actions may be necessary to cover the full anticipated healing time of most wounds (e.g., other fly control methods, barrier methods such as bandaging, repellants).

There are several limitations of the data supporting the benefits of Ivermectin Liquid for Horses (ivermectin oral solution) for the prevention of infestations caused by NWS myiasis in horses. All the clinical studies were conducted in cattle, not horses. The formulation used in the cattle studies was for administration by injection rather than an oral formulation. Extrapolation of effectiveness from cattle to horses may not account for species-related sources of variability in the effect of ivermectin. Furthermore, the studies in cattle 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 Ivermectin Liquid for Horses may differ due to the widespread use of ivermectin and other macrocyclic lactones for the treatment of various internal and external parasites in horses and cattle. Differences in the level of preventative effectiveness between studies in cattle 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 Ivermectin Liquid for Horses for the prevention of NWS infestations should be closely monitored.

The PK profile and published literature support the potential benefit of Ivermectin Liquid for Horses (ivermectin oral solution) for the prevention of infestations caused by NWS myiasis in

horses. The safety profile of ivermectin for horses, including breeding mares, stallions, and foals, is well-characterized and further supported by the bioequivalence study. Veterinary oversight regarding management of parasitism, including NWS larvae (myiasis), should decrease risks associated with effectiveness limitations and antiparasitic resistance.

Warnings and Precautions

User Safety Warnings

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

Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

To obtain a Safety Data Sheet(s), contact Alberta Veterinary Laboratories Ltd (AVL) at 1-877-456-2755 or solvet-us.com/products/ivermectin-liquid-for-horses.

Animal Safety Warnings and Precautions

For use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Swelling and itching reactions after treatment with Ivermectin Liquid for Horses (ivermectin oral solution) have occurred in horses carrying heavy infections of neck threadworm microfilariae (*Onchocerca* sp.). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable.

Environmental Warnings

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.

Other Warnings

Widespread use of any antiparasitic product to prevent NWS myiasis could encourage the development of parasite resistance. When using Ivermectin Liquid for Horses (ivermectin oral solution) for the short-term prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care, veterinary consultation should also address management of the overall parasite program in treated horses, including the treatment and control of other internal and external parasites.

Adverse Reactions

As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to Ivermectin Liquid for Horses (ivermectin oral solution) use under this EUA by:

(1) contacting AVL at 1-877-456-2755 or solvetpharmacomplaints@avetlabs.com,

(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 "Ivermectin Liquid for Horses (ivermectin oral solution) 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**.

Contact Information

For technical assistance, contact Solvet at 1-877-456-2755 or solvet-us.com/products/ivermectin-liquid-for-horses.

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 prevention 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 revocation of the EUA, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Alberta Vet Labs Ltd, HHS, and FDA for inspection upon request.

How Supplied

Ivermectin Liquid for Horses is available in a carton of 25 x 15 mL syringes and 120 mL multi-dose bottles.

Storage Information

Store tightly closed at or below 77°F (25°C). Protect from light.

Manufactured By

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Rev. 07/15/2026