Date of Authorization: July 15, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006681

Ivermectin Liquid for Horses

(ivermectin oral solution)

Horses

Scope of Authorization: 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

Sponsored by:

Alberta Vet Labs Ltd

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I. GENERAL INFORMATION

A. File Number

EUA 006681

B. Sponsor

Alberta Vet Labs Ltd
7226 107 Ave SE
Calgary, Alberta, T2C 5N6, Canada

U.S. Agent Name and Address:

Dr. Aaron Johnson, DVM, MS
Argenta
12707 Shawnee Mission Parkway
Shawnee, KS 66216

C. Proprietary Name

Ivermectin Liquid for Horses

D. Drug Product Established Name

ivermectin oral solution

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Oral solution

G. Amount of Active Ingredient

10 mg/mL

H. How Supplied

25 x 15 mL syringes and 120 mL multi-dose bottles

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

91 mcg of ivermectin per pound (200 mcg/kg) of body weight

K. Route of Administration

Oral or by nasogastric intubation

L. Species

Horses

M. Emergency Authorized Use

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

N. 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.

II. EFFECTIVENESS

A. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the sponsor provided information to support that it is reasonable to believe that Ivermectin Liquid for Horses 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. The evidence supporting effectiveness is based on the pharmacokinetic (PK) profile of Ivermectin Liquid for Horses (ivermectin oral solution) and published scientific literature.

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

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[1] [2].

- 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[3].

Specific plasma levels of ivermectin necessary to prevent NWS myiasis are unknown. However, the Food and Drug Administration (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 in horses 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.

The main assumptions used in the estimation of duration of effectiveness that might be expected with Ivermectin Liquid for Horses (ivermectin oral solution) included that the main effect of ivermectin is on first instar larvae (i.e., little to no effect on repelling flies, eggs, or second and third instar larvae) and that exposure of the first instar larvae to tissues containing an adequate amount of ivermectin for <24 hours would prevent infestation caused by NWS myiasis.

Based on the totality of information provided, 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

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[1] 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.
[2] 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.
[3] 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.

time of most wounds (e.g., other fly control methods, barrier methods such as bandaging, repellants, etc.).

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 (ivermectin oral solution) 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 (ivermectin oral solution) for the prevention of NWS infestations should be closely monitored.

Despite these limitations, this product will provide an additional tool for veterinarians that meets an otherwise unmet need for horses. Navel myiasis in newborn foals is potentially fatal if left untreated, and there are no other systemic products authorized for use in this population. Ivermectin Liquid for Horses (ivermectin oral solution) provides for a route of administration that is not otherwise covered by previous authorizations (oral).

Collectively, the data support that 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.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. For this authorization, target animal safety was established by a comparative blood-level study, which demonstrated that Ivermectin Liquid for Horses (ivermectin oral solution) is bioequivalent to a product previously determined to be safe for horses (EQVALAN® (ivermectin) Liquid for Horses; NADA 140-439).

IV. HUMAN FOOD SAFETY

This drug is intended for use in horses. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for this authorization.

The product Fact Sheet contains the following Warning statement: Do not use in horses intended for human consumption.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to Ivermectin Liquid for Horses:

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.

VI. AGENCY CONCLUSIONS

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, when used as authorized, 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 that the known and potential benefits of Ivermectin Liquid for Horses outweigh the known and potential risks, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae. The benefit of preventing this potentially fatal disease outweighs the health risks of using this product in horses.

There is no adequate, approved,[4] and available alternative to the product for prevention of NWS myiasis in horses.

For additional information on all products authorized or conditionally approved for use to treat and/or prevent New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under Section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under Section 564(c) of the FD&C Act, or other circumstances make such revocation or revision of the authorization appropriate to protect the public health or safety (Section 564(g)(2) of the FD&C Act).

B. Marketing Status

This product is authorized to be dispensed only by or on the order of a licensed veterinarian (Rx marketing status).

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[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.