Fact Sheet: Emergency Use Authorization of Dectomax/Dectomax-CA1 (doramectin injection) for New World Screwworm (NWS)

Horses

Dectomax/Dectomax-CA1 (doramectin injection) is a parasiticide provided as an injectable solution for intramuscular (IM) administration. It contains 10 mg/mL of doramectin.

Original EUA Authorized Date: 05/19/2026

Emergency Use Authorization of Dectomax/Dectomax-CA1 (doramectin 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/conditionally approved products Dectomax/Dectomax-CA1 (doramectin injection) for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older. Dectomax is not approved or conditionally approved for this use.

If infestation develops after doramectin injection administration, alternative treatment is necessary. Dectomax/Dectomax-CA1 is not authorized for the treatment of infestations of NWS in horses.

Dectomax (doramectin injection) is approved for treatment and control of certain nematode and arthropod parasites in cattle and swine (NADA 141-061) and is conditionally approved for NWS indications in cattle (NADA 141-616).

Limitations of Authorized Use

It is a violation of Federal law to use this drug product other than as directed in this fact sheet.

Not for use in horses less than one year of age.

Do not use in horses intended for human consumption.

Dectomax/Dectomax-CA1 (doramectin injection) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Dectomax/Dectomax-CA1 (doramectin 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 the authorization is revoked sooner.

Product Description

Refer to the Dectomax/Dectomax-CA1 (doramectin injection) package insert attached to the vial for full **Product Description** information.

DIRECTIONS

Dectomax/Dectomax-CA1 (doramectin injection) should only be administered by intramuscular (IM) injection at the recommended dosage of 200 mcg doramectin per kg (91 mcg/lb body

weight). Each mL of Dectomax/Dectomax-CA1 contains 10 mg of doramectin sufficient to treat 110 lb of body weight. A maximum of 15 mL should be administered at a single site of injection. If you are unfamiliar with appropriate intramuscular injection technique in horses, please contact your veterinarian for additional assistance.

For the prevention of wound myiasis, administer Dectomax/Dectomax-CA1 at the time of wound appearance. For the prevention of scrotal myiasis, administer Dectomax/Dectomax-CA1 at the time of castration. If a wound is already infested, or an infestation develops after administration of Dectomax/Dectomax-CA1, alternative treatment is necessary.

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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian for appropriate wound care when Dectomax/Dectomax-CA1 is administered to prevent myiasis of a wound.

Dectomax/Dectomax-CA1 (doramectin injection) Dosage Table

Dosage: 200 mcg/kg (1 mL per 110 lbs) by IM injection

Body Weight (lb)	Volume (mL)
440	4.0
550	5.0
660	6.0
770	7.0
880	8.0
990	9.0
1100	10.0
1200	11.0
1300	12.0
1400	13.0

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from pharmacokinetic, clinical effectiveness, and margin of safety studies, it is reasonable to believe that Dectomax/Dectomax-CA1 (doramectin injection) may be effective for the **prevention** of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, and when used under the conditions described in this authorization, the known and potential benefits of Dectomax/Dectomax-CA1 (doramectin injection) outweigh the known and potential risks.

Three dose confirmation studies conducted in the United States in the late 1990s in horses with naturally acquired infections of several gastrointestinal nematodes (worms) support that the proposed dose of 200 mcg/kg body weight administered by IM injection may be effective as an antiparasitic in horses. There is no data in horses demonstrating the prevention of infestations caused by NWS larvae.

Comparative pharmacokinetic information in cattle and horses and clinical data from cattle suggest that a dose of 200 mcg/kg administered IM in horses may be effective for the prevention of infestations caused by NWS larvae. However, there is insufficient information to support a treatment indication or an extended duration of prevention (prevention of reinfestation) in horses. **Therefore, Dectomax/Dectomax-CA1 (doramectin injection) is not authorized for treatment of existing myiasis or for the prevention of reinfestation in horses.**

WARNINGS

User Safety Warnings

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

The safety data sheet (SDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain an SDS, call 1-888-963-8471 or visit https://www.zoetisus.com/product-support/vmips/contact-vmips/.

Animal Safety Warnings

Dectomax/Dectomax-CA1 (doramectin injection) should not be used other than as directed as severe adverse reactions, including fatalities in dogs, may result.

Overdose of Dectomax in horses has been associated with significant adverse reactions including listlessness, depression, drooping lips, mydriasis (dilated pupils), feed held in mouth, weakness, weight shifting, tremors, excitability, ataxia, urine dribbling, head pressing and recumbency. Monitor treated horses for 24-48 hours for any of these signs and contact your veterinarian immediately if they occur.

The active ingredient in Dectomax/Dectomax-CA1 (doramectin injection), is in the same drug class as two dewormers approved for use in horses in the US (ivermectin and moxidectin). It is important not to use Dectomax/Dectomax-CA1 at or near the same time as either of these products, as this could increase the risk of side effects.

Intramuscular injections in horses can be associated with a severe, life-threatening infection in the muscle known as clostridial myositis. Studies conducted to support this authorization did not show any significant injection site reactions; therefore, if your horse develops any significant injection site reactions (pain, swelling, heat), contact your veterinarian immediately to determine whether additional veterinary treatment is necessary.

Safe use of Dectomax/Dectomax-CA1 (doramectin injection) in pregnant or lactating mares and breeding stallions, and horses less than one year of age has not been evaluated.

Environmental Warning

Refer to the Dectomax/Dectomax-CA1 (doramectin injection) package insert attached to the vial for full **Environmental Safety** information.

Other Warnings

Do not use in horses intended for human consumption.

Widespread use of any antiparasitic product to prevent NWS myiasis could encourage the development of parasite resistance. When using Dectomax/Dectomax-CA1 (doramectin injection) for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis), a veterinarian should be consulted for management of the overall parasite program in treated horses, including the treatment and control of other internal and external parasites.

Refer to the Dectomax/Dectomax-CA1 (doramectin injection) package insert attached to the vial for full **Other Warnings** information related to antiparasitic resistance.

Reporting Side Effects

Reporting of side effects potentially related to Dectomax/Dectomax-CA1 (doramectin injection) use under this EUA is strongly encouraged.

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

1. Contact Zoetis Inc. at 1-888-963-8471, 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 “Dectomax 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.[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 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]

Dispensing Status

Over the counter (OTC)

Storage Conditions

Store Below 30ºC (86ºF)

Marketed by:
Zoetis Inc. at 1-888-963-8471
Parsippany, NJ 07054

Rev. 05/19/2026

---

[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
[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