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

Dairy Cattle, Swine, Sheep, and Deer

Dectomax/Dectomax-CA1 (doramectin injection) is a parasiticide provided as an injectable solution for subcutaneous (SC) and 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 following indications:

- the **prevention and treatment** of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal, and

- the **prevention** of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in swine, sheep except for lactating sheep, and deer.

Dectomax is not approved or conditionally approved for these uses.

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 swine, sheep, or deer.

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). Please refer to the Dectomax/Dectomax-CA1 (doramectin injection) package insert attached to the vial for the currently approved and conditionally approved indications in these species.

Limitations of Authorized Use

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

Lactating dairy cows, dry dairy cows, replacement dairy heifers 20 months of age and older, sheep except for lactating sheep, and deer must not be slaughtered for human consumption within 35 days of treatment. Swine must not be slaughtered for human consumption within 24 days of treatment.

Milk that has been taken during treatment and for 468 hours (19.5 days) after treatment must not be used 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 and heifers must not be processed for veal.

Not for use in lactating sheep. Use in these sheep may cause drug residues in milk.

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

Prevention and Treatment

For dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), Dectomax/Dectomax-CA1 (doramectin injection) should be administered by subcutaneous (SC) injection only at the recommended dosage of 200 mcg per kg body weight. Each mL of Dectomax/Dectomax-CA1 contains 10 mg of doramectin sufficient to treat 110 lb of body weight.

In dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), if a wound is already infested or larvae appear after Dectomax/Dectomax-CA1 administration, physical removal of larvae is required.

Prevention

For swine, Dectomax/Dectomax-CA1 (doramectin injection) should be administered by intramuscular (IM) injection only at the recommended dosage of 300 mcg per kg body weight. Each mL of Dectomax/Dectomax-CA1 contains 10 mg of doramectin sufficient to treat 75 lb of body weight.

For sheep except for lactating sheep, Dectomax/Dectomax-CA1 (doramectin injection) should be administered by IM or SC injection at the recommended dosage of 200 mcg per kg body weight. Each mL of Dectomax/Dectomax-CA1 contains 10 mg of doramectin sufficient to treat 110 lb of body weight.

For deer, Dectomax/Dectomax-CA1 (doramectin injection) should be administered by SC injection only at the recommended dosage of 200 mcg per kg body weight. Each mL of Dectomax/Dectomax-CA1 contains 10 mg of doramectin sufficient to treat 110 lb of body weight.

For the prevention of wound myiasis, administer Dectomax/Dectomax-CA1 (doramectin injection) at the time of wound appearance. For the prevention of scrotal myiasis, administer Dectomax/Dectomax-CA1 at the time of castration. To prevent shearing wound myiasis in

sheep, administer Dectomax/Dectomax-CA1 at the time of shearing. If a wound is already infested, or if an infestation develops after Dectomax/Dectomax-CA1 administration, 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 Tables

Animal	Route	Dosage	Volume
Dairy Cattle*	SC	200 mcg/kg	1 mL per 110 lbs
Sheep**	IM or SC	200 mcg/kg	1 mL per 110 lbs
Deer	SC	200 mcg/kg	1 mL per 110 lbs
Swine	IM	300 mcg/kg	1 mL per 75 lbs

Body Weight (lb)	Dairy Cattle* (mL)	Sheep** / Deer (mL)	Swine (mL)
15	-	0.1	0.2
30	-	0.3	0.4
45	-	0.4	0.6
60	-	0.5	0.8
75	-	0.7	1.0
110	1.0	1.0	1.5
150	1.4	1.4	2.0
220	2.0	2.0	2.9
300	2.7	2.7	4.0
330	3.0	3.0	4.4
440	4.0	-	5.9
550	5.0	-	7.3
660	6.0	-	-
770	7.0	-	-
880	8.0	-	-
990	9.0	-	-
1100	10.0	-	-
1200	11.0	-	-
1300	12.0	-	-
1400	13.0	-	-
1500	14.0	-	-

*Dairy Cattle (lactating dairy cows, dry dairy cows and replacement dairy heifers 20 months of age and older)
**Sheep except for lactating sheep.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data and information from pharmacokinetic, clinical effectiveness, and margin of safety studies, and published scientific literature, it is reasonable to believe that Dectomax/Dectomax-CA1 (doramectin injection) may be effective for the **prevention and treatment** of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the **prevention** of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in swine, sheep except for lactating sheep, and deer, 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.

For dairy cattle, lactating cows, particularly those with high milk production, there were differences in drug clearance as compared to non-lactating animals. For this reason, it could not be assumed that the effectiveness data in non-lactating cattle against NWS, as provided under the conditional approval of Dectomax-CA1 (NADA 141-616), could be directly applied to lactating dairy cattle. Therefore, a pharmacokinetic (PK) approach was used, with further work done utilizing physiologically based pharmacokinetic modeling (PBPK). This PBPK modeling allowed comparison between the plasma levels of injectable doramectin in non-lactating cattle to lactating cattle. This modeling indicated that both lactating and non-lactating cattle appear to have very similar rapid increases in doramectin plasma levels within the first day of administration and that doramectin plasma levels in lactating cattle appear to be higher within the first week after administration as compared to non-lactating cattle. PBPK modeling showed that lactation in cattle may result in a more rapid clearance of doramectin, and blood levels of doramectin at 21 days are likely to be lower in lactating animals. This information coupled with the clinical effectiveness data in NWS to support both a prevention and treatment indication under cNADA 141-616 provided enough evidence to reasonably conclude that Dectomax/Dectomax-CA1 may be effective for the prevention and treatment of infestations caused by NWS myiasis in dairy cattle. There was not enough evidence to support that doramectin may be effective in dairy cattle for 21 days, therefore, a prevention of reinfestation for 21 days indication was not granted. It was concluded that the safety information submitted under NADA 141-061 for the full approval of Dectomax for various endo- and ectoparasites in cattle supports the safety of doramectin injectable in dairy cattle as well.

Three dose confirmation (clinical effectiveness) studies conducted in Brazil and Argentina in 1996 and 1997 evaluated the effectiveness of Dectomax (doramectin injection) for the prevention of infestations caused by NWS larvae (myiasis) in sheep. These studies support that the proposed dose of 200 mcg/kg body weight administered by IM or SC injection is effective for the prevention of NWS in sheep.

One study published in the scientific literature evaluated the effectiveness of a single subcutaneous dose of 200 mcg doramectin/kg BW for the prevention of natural infestations caused by NWS larvae (myiasis) in sheep[1].

[1] Sanavria, A. and Prata, M.C.A. (1996). Prophylactic efficacy of doramectin against natural infestations by *Cochliomyia hominivorax* in sheep post-castration. *Brazilian Journal of Veterinary Research and Animal Science. 33*(3): 163-166

Safety and effectiveness studies for various parasites were conducted in swine, including reproductive safety studies in neonates. See the FOI Summary for NADA 141-061 for study summary information. There is no data in swine demonstrating the prevention of infestations caused by NWS larvae. Comparative pharmacokinetic information between sheep and deer, between sheep and swine, and clinical data from sheep suggest that a dose of 200 mcg/kg administered SC in deer, and 300 mcg/kg administered IM in swine, 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 swine, sheep, and deer. **Therefore, Dectomax/Dectomax-CA1 (doramectin injection) is not authorized for treatment of existing myiasis or for the prevention of reinfestation in swine, sheep, and deer.**

Limitations of the data in sheep are that all the studies were conducted in Argentina and Brazil and were conducted prior to 2000. The susceptibility of current field isolates of NWS larvae to treatment with Dectomax/Dectomax-CA1 (doramectin injection) may differ due to the widespread use of other macrocyclic lactones for the treatment of various internal and external parasites in sheep.

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 periods and milk discard time.

WARNINGS

Withdrawal Periods, Milk Discard Time, and Residue Warnings:

Lactating Dairy Cows, Dry Dairy Cows, Replacement Dairy Heifers: Milk that has been taken during treatment and for 468 hours (19.5 days) after treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 35 days of treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows and heifers must not be processed for veal.

Swine: Swine must not be slaughtered for human consumption within 24 days of treatment.

Sheep: Sheep must not be slaughtered for human consumption within 35 days of treatment. Not for use in lactating sheep. Use in these sheep may cause drug residues in milk.

Deer: Deer must not be slaughtered for human consumption within 35 days of treatment.

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/.

Precautions

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

Refer to the Dectomax/Dectomax-CA1 (doramectin injection) package insert attached to the vial for full **Precautions** information in swine and cattle.

Environmental Warning

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

Other Warnings

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 animals, 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[2].

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.[3]

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

[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

[3] 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

- 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,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

Dispensing Status

Over the counter (OTC)

Storage Conditions

Store Below 30ºC (86ºF)

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

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