Fact Sheet: Emergency Use Authorization of Nitenpyram Tablets (nitenpyram) for New World Screwworm (NWS)

Nitenpyram Tablets contain 11.4 or 57.0 mg of nitenpyram for oral administration. Nitenpyram belongs to the chemical class of neonicotinoids and kills adult fleas.

Revised EUA Authorized Date: 09/03/2026

Emergency Use Authorization of Nitenpyram Tablets (nitenpyram) 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 Nitenpyram Tablets (nitenpyram) for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older**. Nitenpyram Tablets are not approved for this use.

Nitenpyram Tablets (nitenpyram) (ANADA 200-858) are approved for other uses in dogs, puppies, cats and kittens.[1]

Limitations of Authorized Use

Nitenpyram Tablets (nitenpyram) are not authorized for use in dogs, puppies, cats and kittens less than 2 pounds of body weight or 4 weeks of age.

Nitenpyram Tablets (nitenpyram) are authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Nitenpyram Tablets (nitenpyram) 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

Nitenpyram Tablets are oral tablets for dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older**.

Refer to the Nitenpyram Tablets package insert for full **Product Description** information.

Directions and Other Information

To give Nitenpyram Tablets, place the pill directly in your pet's mouth or hide it in food. If you hide it in food, watch closely to make sure your pet swallows the pill. If you are not sure that your pet swallowed the pill, it is safe to give a second pill.

Weigh your pet prior to administration to ensure proper dosage. Do not administer to pets under 2 pounds. Refer to the Nitenpyram Tablets package insert (**Post-Approval Experience**) for important safety information.

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[1] Nitenpyram Tablets are approved to kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.

Recommended Dosage Schedule:

Species	Body Weight	Dose	Nitenpyram per Tablet
Dog or Cat	2-25 lbs.	One Tablet	11.4 mg
Dog	25.1-125 lbs.	One Tablet	57.0 mg

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

Treatment:
Nitenpyram Tablets should be administered according to the Recommended Dosage Schedule above. **A second dose should be administered 6 hours after the first.**

For effective treatment of NWS fly larvae (maggots) in a wound, Nitenpyram Tablets should be used in addition to the physical removal of maggots (live and dead), by a veterinarian, remaining in the wound after treatment. Consult your veterinarian to ensure appropriate wound care, including cleansing of the wound, surgical removal of dead, infected, or damaged tissue, and pain management, as needed.[2]

The lifecycle of the *C. hominivorax* fly is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. **Pets may become reinfested following treatment.**

Other information:
- Gloves should be worn if you are cleaning the wound, the pet's bedding, or disposing of maggots.
- Pets should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live maggots may exit the wound and be left on bedding or areas where your pet sits or lies after treatment.
- Maggots that fall off your pet should be placed in a sealed container with rubbing alcohol.
- If there is worsening of the wound, you should contact your veterinarian.

Prevention:
Nitenpyram Tablets should be administered once daily according to the Recommended Dosage Schedule above. Nitenpyram Tablets must be administered daily to prevent NWS infestations.

Nitenpyram Tablets do not kill adult flies, prevent adult flies from laying eggs, or prevent eggs from hatching.

Daily administration of Nitenpyram Tablets prevents NWS infestations by killing newly hatched maggots within 24 hours of dosing.

[2] Cutolo, A. A., Perier, N., Menz, I., Thyssen, P., Silva, F. O., & Beugnet, F. (2021). Efficacy of afoxolaner (NexGard) on the treatment of myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Veterinary parasitology, regional studies and reports*, *24*, 100569.

The safety of daily administration of Nitenpyram Tablets to puppies and kittens for more than 6 months and to dogs and cats for more than 9 months has not been evaluated.

Refer to the Nitenpyram Tablets package insert for safety information related to redosing (**Directions**), use in pregnant or nursing dogs and cats (**Other Information, Post-Approval Experience**), and use together with other products (**Other Information**).

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from published literature, it is reasonable to believe that Nitenpyram Tablets (nitenpyram) may be effective for the treatment and prevention of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older**, and when used under the conditions described in this authorization, the known and potential benefits of Nitenpyram Tablets (nitenpyram) outweigh the known and potential risks.

Treatment:
A study conducted in Brazil,[3] evaluated seven laboratory beagles with naturally acquired *C. hominivorax* maggot infestations. All dogs received nitenpyram by mouth followed by a second dose 6 hours after the first. Eighty-six percent of maggots were expelled from the wounds 6 hours after the first dose and 95.3% were expelled 18 hours after the first dose. Eighteen hours after the first dose, the maggots remaining in the wound were physically removed and found to be dead.

Another study[4] evaluated 40 privately owned dogs with naturally acquired presumptive *Chrysomya bezziana* (Old World screwworm) maggots. Eight dogs received nitenpyram by mouth. All dogs that received nitenpyram had complete resolution of their infestation by 6 hours after dosing. The average speed of onset to maggot expulsion was 2.4 hours and the average time for complete resolution of maggot infestation was 5.4 hours.

A published case report series[5] briefly describes the treatment and outcome of five cats in Brazil with naturally acquired *C. hominivorax* maggot infestations. Three unowned cats had massive maggot infestations in extensive wounds. Two client-owned cats, previously treated with surgery, had maggot infestations in their surgical sites 18 to 36 days after surgery. Dead tissue and accessible maggots were promptly removed, and nitenpyram was administered to all cats. A few hours after dosing, the maggots actively left the wound in all cats. Maggots that were deeper in the wound and not expelled required physical removal.

Prevention:
NWS infestations begin when a female fly lays eggs on open wounds or other parts of the body in live, warm-blooded animals. One adult fly can lay 200 to 300 eggs at a time and up to 3,000

[3] Correia, T. R., Scott, F. B., Verocai, G. G., Souza, C. P., Fernandes, J. I., Melo, R. M., Vieira, V. P., & Ribeiro, F. A. (2010). Larvicidal efficacy of nitenpyram on the treatment of myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in dogs. *Veterinary Parasitology*, *173*(1-2), 169–172.
[4] Han, H.S., Chen, C., Schievano, C., & Noli, C. (2018). The comparative efficacy of afoxolaner, spinosad, milbemycin, spinosad plus milbemycin, and nitenpyram for the treatment of canine cutaneous myiasis. *Veterinary Dermatology*, 10.1111/vde.12548.
[5] de Souza, C. P., Verocai, G. G., & Ramadinha, R. H. (2010). Myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in cats from Brazil: report of five cases. *Journal of feline medicine and surgery*, *12*(2), 166–168.

eggs during her 10- to 30-day lifespan. The eggs hatch in 12 to 24 hours depending on environmental conditions. Once hatched, the maggots burrow into the wound to feed on living tissue. The maggots progress through three life stages over 5 to 7 days. Once maggots reach the third stage, the maggots fall from the wound, burrow into the ground, and emerge as adult flies in 7 to 54 days depending on temperature and humidity.

Nitenpyram Tablets do not kill or repel adult flies, prevent adult flies from laying eggs, prevent eggs from hatching, or prevent newly hatched maggots from feeding. Daily administration of Nitenpyram Tablets prevents establishment of NWS infestations by killing newly hatched maggots within 24 hours of dose administration.

WARNINGS

User Safety Warnings

Not for human use. Keep this and all drugs out of the reach of children. Keep Nitenpyram Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

To obtain a Safety Data Sheet (SDS), contact Felix Pharmaceuticals Private Limited at 1-833-571-1525 or www.felixvet.com.

Animal Safety Warnings

Refer to the Nitenpyram Tablets package insert for full **Adverse Reaction** and **Post-Approval Experience** information.

Reporting Side Effects

Reporting of side effects potentially related to Nitenpyram Tablets use under this EUA is strongly encouraged.

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

1. Contact Felix Pharmaceuticals Pvt. Ltd. at 1-833-571-1525, 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 “Nitenpyram Tablets 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.[6]

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.[7]

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

[6] 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

[7] 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

- There is no adequate, approved,[8] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[9]

Dispensing Status

Over the counter (OTC)

Storage Conditions

Refer to the Nitenpyram Tablets package insert for full **Storage Conditions** information.

Distributed by:
Felixvet Inc.,
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Manufactured in India

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[8] "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.
[9] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization