Fact Sheet: Emergency Use Authorization of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) for New World Screwworm (NWS)

F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) is intended for use in cattle, horses, minor species[1] of hoof stock, raptors and other wild birds, pet birds, and captive and captured[2] wild, exotic, and zoo mammals and contains benzalkonium chloride 0.405 g/100 mL, polyhexanide 0.03 g/100 mL, and cypermethrin 0.25 g/100 g.

Original EUA Authorized Date: 04/24/2026

Emergency Use Authorization of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the indexed product F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals. F10 Antiseptic Barrier Ointment with Insecticide is not approved or indexed for this use.

F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) is indexed for use as a topical antiseptic for surface wounds, to repel flies and to treat infestations due to fly strike in raptors, pet birds, captive small mammals, captive reptiles and captive exotic/zoo mammals (Minor Species Index File (MIF) 900-011).[3]

Limitations of Authorized Use

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

Cattle, goats, and sheep must not be slaughtered for human consumption within 30 days of treatment.

For non-domesticated minor species hoof stock,[4] use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 30 days of treatment.

Milk taken from cows, goats, or sheep during treatment and for 10 days after treatment must not be used for human consumption.

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[1] Minor species are all animals, other than humans, that are not one of the major species. They include animals such as zoo animals, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, and game birds, among others. The term 'major species' means cattle, horses, swine, chickens, turkeys, dogs, and cats.

[2] Definitions for "captive wildlife" and "captured wildlife" can be found in the last section of the USDA APHIS New World Screwworm Response Playbook, accessible at https://www.aphis.usda.gov/animal-emergencies/nws.

[3] See FDA's webpage "The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species" at https://www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species

[4] For example, deer, elk, antelope, and nilgai.

A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

Do not use in horses intended for human consumption.

Do not use in domestic dogs and cats.

Do not use in food-producing species that have not been assigned a withdrawal period, as listed in the Withdrawal Periods and Residue Warnings section of the authorized Fact Sheet.

F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) 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

F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) is an opaque, white, semi-solid ointment.

Directions

Use disposable gloves during application and wash hands thoroughly after use. Clean the wound prior to application. Apply a layer of ointment over the entire wound site. Repeat once a week, if necessary or as advised by your veterinarian.

This product is water soluble and should be reapplied if animal is bathed or exposed to rain. If the wound persists or worsens, contact your veterinarian.

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

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including information submitted in support of the Minor Species Index File (MIF 900-011) and this EUA, as well as publicly available information, it is reasonable to believe that F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive and captured wild, exotic, and zoo mammals, and when used under the conditions described in the authorization, the known and potential benefits of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) outweigh the known and potential risks.

Information to support the effectiveness of F10 Antiseptic Barrier Ointment with Insecticide under MIF 900-011 were primarily conducted using blowfly species common in South Africa, including *Lucilia cuprina*, the Australian sheep blowfly. (For further details, see the FOI

Summary for MIF 900-011.) Cypermethrin, the insecticide in F10 Antiseptic Barrier Ointment with Insecticide, has documented activity against several other fly species as well, including fly species which are known to cause myiasis in mammals. There is no direct evidence that F10 Antiseptic Barrier Ointment with Insecticide is effective against *C. hominivorax*. However, both *C. hominivorax* and *L. cuprina* blowflies belong to the family Calliphoridae and generally, blowflies have similar life cycles and morphology. Additionally, the indexed product is labeled for use as a topical antiseptic for surface wounds; it is reasonable to believe that this product would also function as an antiseptic for wounds in cases of NWS myiasis, reducing the risk of secondary infection. Therefore, it is reasonable to conclude that F10 Antiseptic Barrier Ointment with Insecticide may be effective for the prevention and treatment of NWS myiasis.

The FOI Summary for MIF 900-011 also contains a summary of the safety information regarding the use of F10 Antiseptic Barrier Ointment with Insecticide in raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals. The anecdotal evidence provided there shows that F10 Antiseptic Barrier Ointment with Insecticide has been used safely outside of the U.S. in cattle and numerous minor species of cloven-hoofed (ungulate) mammals such as sheep, goats, deer, buffalo, bison, and antelope. Therefore, it is reasonable to conclude that the benefits of using this product in cattle and minor species of hoof stock outweighs the risks.

Cypermethrin is contained in several products registered by the U.S. Environmental Protection Agency (EPA) for use in horses. Potential adverse reactions include hypersensitivity reactions (including urticaria and pruritus) and hair loss. The benefits in horses of using F10 Antiseptic Barrier Ointment with Insecticide, which contains cypermethrin, outweighs these risks because myiasis is a potentially deadly disease.

F10 Antiseptic Barrier Ointment with Insecticide is currently indexed for raptors, pet birds, captive small mammals, captive reptiles, and captive exotic/zoo mammals when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals. It is reasonable to include these animals under the EUA; however, captive reptiles are not susceptible to NWS; therefore, they are not included in the list of species authorized for NWS.

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 period and milk discard time listed below.

WARNINGS

Withdrawal Periods and Residue Warnings: Cattle, goats, and sheep must not be slaughtered for human consumption within 30 days of treatment. For non-domesticated minor species hoof stock, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 30 days of treatment. Milk taken from cows, goats, or sheep during treatment and for 10 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 must not be processed for veal.

User Safety Warnings

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

Do not use with soaps or other chemicals.

Use disposable gloves during application and wash hands thoroughly after use. Do not contaminate food, water, eating utensils, or food contact surfaces. Wash hands before eating or drinking. If accidentally ingested, contact a Poison Control Center or a doctor. Do not induce vomiting unless advised by the Poison Control Center or a doctor. If accidental eye contact occurs, hold eye open and rinse with water for 10 minutes. Seek medical help if necessary.

To obtain Safety Data Sheets (SDS), contact Health and Hygiene (Pty) Ltd at 1-800-517-4705 or https://f10products.com.

Animal Safety Warnings

Possible side effects that may occur include the development of hives, itchiness, and hair loss. If any of these signs occur, discontinue use of the product on that animal and contact your veterinarian.

Environmental Warnings

This product is extremely toxic to fish, aquatic invertebrates, oysters and shrimp. Do not apply directly to or near water.

Other Warnings

Do not use in horses intended for human consumption.

Do not use in domestic dogs and cats.

Do not use in food-producing species that have not been assigned a withdrawal period, as listed in the Withdrawal Periods and Residue Warnings section.

Resistance can develop to any drug used to treat and prevent NWS myiasis. Reports in scientific literature provide evidence of the development of resistance to pyrethrins such as cypermethrin in *C. hominivorax* populations in South America. The effectiveness of F10 Antiseptic Barrier Ointment with Insecticide for the prevention and treatment of NWS infestations should be closely monitored. If the wound is not healing properly, consult your veterinarian.

Reporting Side Effects

Reporting of side effects potentially related to F10 Antiseptic Barrier Ointment with Insecticide use under this EUA is strongly encouraged.

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

1. Contact Health and Hygiene (Pty) Ltd at 1-800-517-4705 or https://f10products.com, 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 "F10 Antiseptic Barrier Ointment with Insecticide 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.

Contact Information

For technical assistance, contact Health and Hygiene (Pty) Ltd at 1-800-517-4705 or https://f10products.com.

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.[5]

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

[5] 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

or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[6]

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,[7] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[8]

How Supplied

3.5 oz (100 g) and 17.6 oz (500 g) jars

Dispensing Status

Over the counter (OTC)

Storage Conditions

Store between 15° to 30°C (59° to 86°F) in dry conditions.

Do not reuse container. If empty, place in trash or recycle if available. If partly filled, contact your local solid waste agency for disposal instructions.

Manufactured by:
Health and Hygiene (Pty) Ltd
Cnr. Leader & Hoefsmid Streets
Stormill Ext. 10
South Africa
1-800-517-4705
https://f10products.com

Rev. 06/22/2026

[6] 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
[7] "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.
[8] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.