

PMRA Approved Label
2024-0563
2025-12-10

(Sublabel A: Amiflex product packaged with applicator)

GROUP	19	INSECTICIDE
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Amiflex[®]

COMMERCIAL

INSECTICIDE

Gel

Amiflex[®] by Veto-Pharma
Veto-Pharma committed to Apiculture
Gel formulation for the in-hive suppression of phoretic varroa mites on honey bees

ACTIVE INGREDIENT: Amitraz..... 1.99 %

REG. N°. 35751 PCP ACT

READ LABEL AND ATTACHED BROCHURE BEFORE USING

NET CONTENTS:

Contains 10 syringes each containing 120 mL of Amiflex[®], [1 dosing gun] and 400 supports [tongue depressors]

[Expiration date: 24 months]

Batch number/Date of manufacture: See on container

Registrant in Canada and owner of the product and trademark Amiflex[®]:

Véto-pharma SAS

12-14 rue de la Croix-Martre 91120 Palaiseau France

info@vetopharma.com

Public Inquiries:

Technology Sciences Group (TSG) Canada Inc. (dba Sagentia Regulatory)

6th Floor, Tower B, Suite 600

380 Wellington St, London ON, N6A 5B5

Canada

+1 202 828 8990

GENERAL:

Amiflex® is a product specifically designed for use in beehives. The easy-to-use dosing gun ensures correct dosage of the active ingredient amitraz. Amiflex® has no harmful effect on the honey bee colony, neither on brood nor on adults, when used according to directions. It ensures no residues in honey beyond the maximum limits when used according to directions.

FIRST AID:

If on Skin/clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control centre or doctor for further treatment advice.

If swallowed: Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION:

Amitraz acts primarily as an α 2-adrenergic receptor agonist. Symptoms of poisoning may include central nervous system depression (drowsiness, dizziness, and decreased heart rate), skin irritation, eye irritation, and transient skin flushing. Phentolamine and Yohimbine may be useful antidotes.

PERSONAL PROTECTIVE EQUIPMENT

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during application and clean up. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL PRECAUTIONS:

Toxic to aquatic organisms.

RESISTANCE-MANAGEMENT RECOMMENDATIONS:

For resistance management, Amiflex® contains a Group 19 acaricide. Any mite population may contain individuals naturally resistant to Amiflex® (amitraz) and other similar miticides from group 19. The resistant individuals may dominate the mite population if this amitraz-based miticide is used repeatedly in the same location. Other resistance mechanisms that are not linked to site of action but are specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay miticide resistance:

- Where possible, rotate the use of Amiflex® or other similar miticides from group 19 with different groups that control the same pests.
- Miticide use should be based on an Integrated Pest Management (IPM) program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.

- Correctly identify the pest and ensure economic and agronomic thresholds are met before treatment.
- Monitor treated pest populations for resistance development.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.
- For further information or to report suspected resistance contact your local extension specialist.

STORAGE:

Store this product away from food or feed. Store unopened syringes in a cool, dry area, out of direct sunlight, and away from other pesticides that may contaminate the product. Use the syringe immediately after its first opening and discard any unused product.

DISPOSAL:

Dispose of packaging and used product in accordance with provincial or territorial requirements. For information on disposal of unused, unwanted product, contact the registrant or the provincial or territorial regulatory agency. Contact the registrant and the provincial or territorial regulatory agency in case of a spill, and for clean-up of spills.

Shelf life: when stored appropriately, this product should show no significant degradation for two years from date of manufacture.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Dispose of in a sanitary landfill or by incineration. Do not burn unless allowed by provincial or territorial and local ordinances.

NOTICE TO USER:

This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label.

(brochure)

GROUP 19 INSECTICIDE

Amiflex®

COMMERCIAL
INSECTICIDE

Gel

Amiflex® by Veto-Pharma

Veto-Pharma committed to Apiculture

Gel formulation for the in-hive suppression of phoretic varroa mites on honey bees

ACTIVE INGREDIENT: Amitraz1.99 %

REG. N°. 35751 PCP ACT

READ LABEL AND ATTACHED BROCHURE BEFORE USING

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GENERAL INFORMATION

Amiflex® is a product specifically designed for use in beehives. The easy-to-use dosing gun ensures correct dosage of the active ingredient amitraz. Amiflex® has no harmful effect on the honeybee colony, neither on brood nor on adults, when used according to directions. It ensures no residues in honey beyond the maximum limits when used according to directions.

DIRECTIONS FOR USE

READ ENTIRE LABEL BEFORE USING THIS PRODUCT.

Read entire label, use strictly in accordance with precautionary statements and directions, and with applicable provincial or territorial and federal regulations.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Amiflex® is a gel formulation designed for use in beehives to suppress the parasitic mite (*Varroa destructor*) sensitive to amitraz on honeybees.

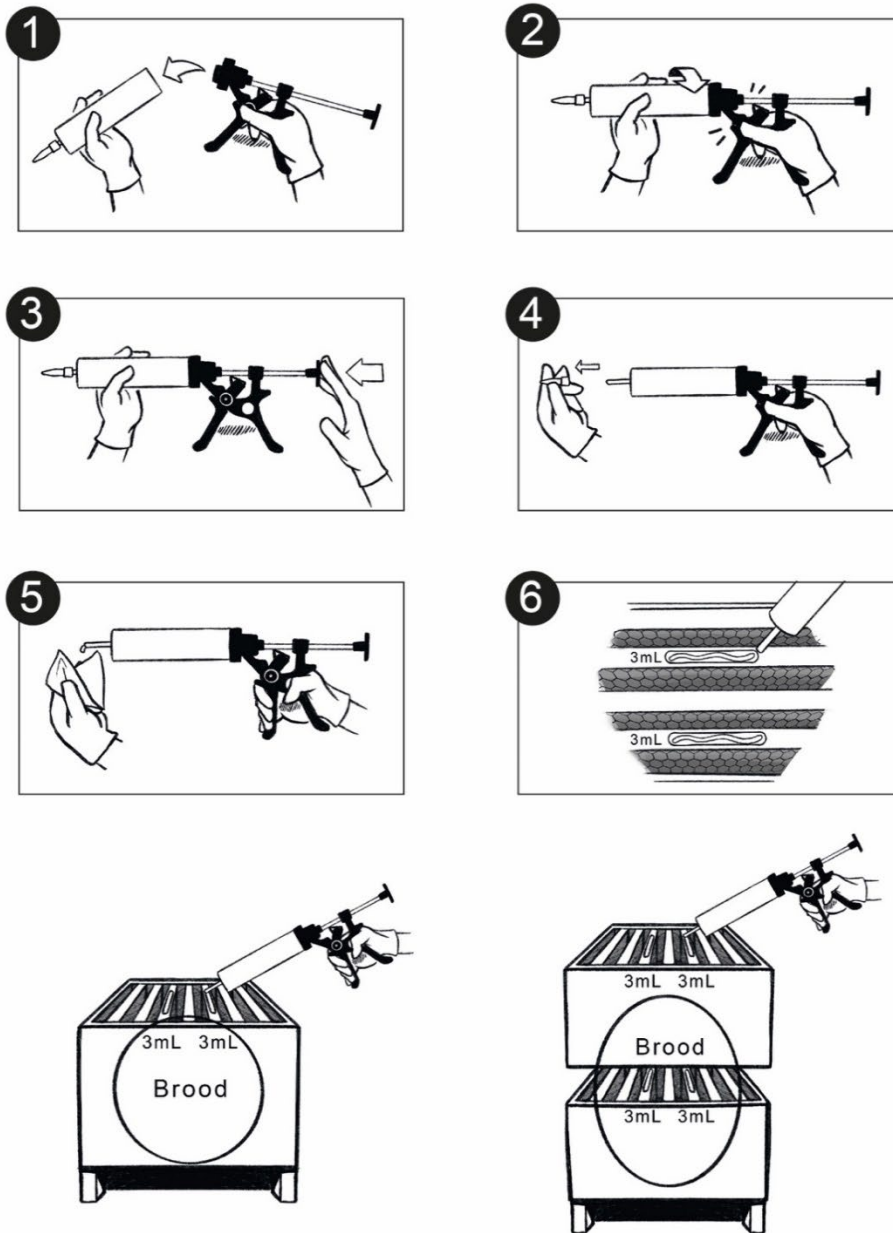
Loading of Dosing gun – Load and secure Amiflex® syringe into dosing gun [see pictures 1, 2, 3]. Remove the cap of the syringe [see picture 4]. Gently and briefly depress trigger several times to prime tool ready for application of product to hives [picture 5]. Each pull of the trigger delivers a standard dose of 3 mL of product. Apply 2 doses of 3 mL per brood chamber. When product syringe is empty, replace with new product syringe. Retain dosing gun for future applications of Amiflex®.

How to Apply - Amiflex® can be used to treat phoretic varroa mites both in brood free colonies and when brood is present, however Amiflex® does not affect mites in capped brood cells. Amiflex® cannot be used in presence of honey supers.

Scrape frames clear of all excess wax and propolis that could prevent the bees from coming into contact with the gel, for example, clean top feeders, top bars, or for a double broodchamber hive, below the frames for the top broodchamber.

Set two supports [tongue depressors] [included] per broodchamber on the top bars of frames in the center of the brood area or in the center of the bee cluster. Avoid end frames for application. For a better distribution of the active ingredient in the colony, leave a minimum of one frame free of gel between two frames with gel.

Use the dosing gun to apply 2 doses of 3 mL of Amiflex® by applying a line of gel on each support [tongue depressor] [See picture 6]. For a double broodchamber hive, the total dosage will be 4 lines of 3 mL (i.e a total of 12 mL) of gel.



[Image of instruction to user on placement of Amiflex]

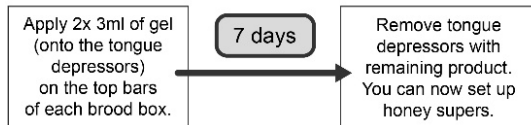
Application Timing:

This product is designed to reduce the load of phoretic mites with quick knockdown action. Amiflex[®] does not replace a long action product, especially for a late-summer treatment. The product can be used any time when honey supers are not present and as long as the bees are active in the hives (avoid winter treatment). Do not use during honey flow. Due to its quick action, the product can be used two times during the year in order to limit the mite exponential growth of mite populations. Apply Amiflex[®] a maximum of two times per colony per year, either as two applications 14 days apart before a single honey flow, or as two separate applications (7-day each) at different times during the year. If varroa infestation is high: apply a second application 7 days after removing the first one in order to

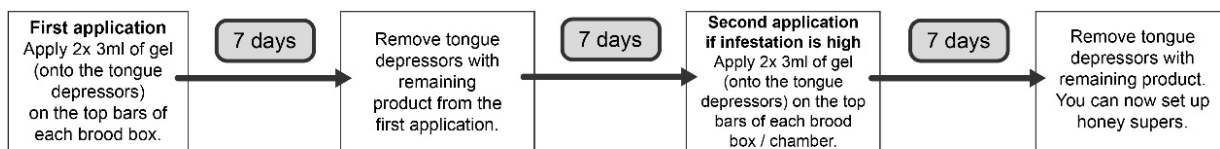
cover new emerging bees. Do not apply Amiflex® more than two times in a row before one honey flow.

Amiflex® can also be applied 7 days before applying a long action treatment, to obtain a knockdown effect before such treatment.

In case of low infestation or before a long-action treatment:



In case of high infestation:



Withholding period for honey collection:

DO NOT USE AMIFLEX® WHEN HONEY SUPERS ARE PRESENT.

The treatment period is 7 days. After the 7 days, remove the potential treatment leftover and supports [tongue depressors]. The honey supers can now be set-up.

Resistance-management:

For resistance management, Amiflex® contains a Group 19 acaricide. Any mite population may contain individuals naturally resistant to Amiflex® (amitraz) and other similar miticides from group 19. The resistant individuals may dominate the mite population if this amitraz-based miticides is used repeatedly in the same location. Other resistance mechanisms that are not linked to site of action but are specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay miticide resistance:

- Where possible, rotate the use of Amiflex® or other similar miticides from group 19 with different groups that control the same pests.
- Miticide use should be based on an Integrated Pest Management (IPM) program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.
- Correctly identify the pest and ensure economic and agronomic thresholds are met before treatment.
- Monitor treated pest populations for resistance development.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.
- For further information or to report suspected resistance contact your local extension specialist.

RESTRICTIONS:

- For in-hive use only.
- Do not use Amiflex® on sparsely populated and inactive colonies.
- Do not use Amiflex® when honey supers are present.
- Remove honey supers before application of Amiflex®.
- Maximum rate per application = 2 x 3 mL (6 mL) per broodchamber per application
- Remove the treatment leftover and supports [tongue depressors] before placing honey supers
- Do not use Amiflex® more than twice a year

- Do not use Amiflex® more than 2 times in a row before one honey flow.

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If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control centre or doctor for further treatment advice.

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PERSONAL PROTECTIVE EQUIPMENT

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during application and clean up. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL PRECAUTIONS:

Toxic to aquatic organisms.

STORAGE:

Store this product away from food or feed. Store at ambient room temperature, out of direct sunlight, and away from other pesticides that may contaminate the strips.

DISPOSAL:

Dispose of packaging and used syringes and supports [tongue depressors] in accordance with provincial or territorial requirements. For information on disposal of unused, unwanted product, contact the registrant or the provincial or territorial regulatory agency. Contact the registrant and the provincial or territorial regulatory agency in case of a spill, and for clean-up of spills. Shelf life: when stored appropriately, this product should show no significant degradation for two years from date of manufacture.

NOTICE TO USER:

This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label.

(Sublabel C: Label language for individual product syringe tubes)

Amiflex®

COMMERCIAL
INSECTICIDE

ACTIVE INGREDIENT: Amitraz 1.99 %

REG. N°. 35751 PCP ACT

READ LABEL AND ATTACHED BROCHURE BEFORE USING

(Note to Reviewer : Optional Logos and Marketing Statements below)

[committed to apiculture]



[Image of honeybee]

Manufacturing Claims

- 1) An innovative amitraz based product [specifically designed] for [honey] bees
- 2) First amitraz flash treatment [for honey bees] [for commercial beekeepers]
- 3) First [approved] [authorized] amitraz flash treatment [for honey bees] [for commercial beekeepers]
- 4) An [approved] [authorized] flash treatment [for honey bees] [for commercial beekeepers]
- 5) An [approved] [authorized] product to flash-treat your hives with amitraz
- 6) When used according to the label directions, Amiflex[®] provides consistent results, is not harmful to bees, and meets or exceeds stringent [manufacturing] quality standards.
- 7) Formulated by beekeeping experts for beekeepers
- 8) Vété-pharma controls the entire Amiflex production chain from the supply of primary materials to release on the market. This means that Vété-pharma can guarantee the high quality of Amiflex, in accordance with regulations in the different countries where the product is registered.
- 9) High-quality product
- 10) Strict analysis and Quality Control process of each batch before marketing.

Mode of Action Claims

- 11) A flash treatment like Amiflex[®] kills [phoretic] varroa mites during the treatment period. As a result, the mite infestation of the colony quickly decreases.
- 12) [Knockdown] [flash action]
- 13) Amiflex[®] is effective to suppress mite infestation
- 14) Amiflex[®] effectively reduces the mite infestation pressure during the season.
- 15) “Knockdown effect” to [quickly reduce the mite load of a colony] [reduce the mite pressure].
- 16) Amiflex[®] reduces the mite infestation level during the season to prevent an excessive infestation before the late-summer or fall treatment.
- 17) Amiflex[®] helps to prepare honey bee colonies for a successful overwintering by reducing mites levels during the season.
- 18) Amiflex[®] can be applied 7 days before applying a long action treatment to obtain a knockdown effect before the long action treatment.
- 19) Amitraz is a miticide that paralyzes Varroa mites. Varroa can no longer hold on to the bees and fall to the hive’s bottom, leading to their starvation.

20) Amiflex® works by contact: As bees [get] [move] in contact with the gel, they pick up molecules of the active ingredient and then distribute them throughout the colony.

Application Claims

- 21) Easy and fast to apply
- 22) Labour-saving [thanks to a quick in-hive application] [due to a ready-to-use formulation and dosing gun]
- 23) Ready-to-use formulation: no mixing of product required.
- 24) Fast application thanks to the dosing gun delivering the exact dose required (3 mL)
- 25) Designed to prevent direct contact with [the active ingredient] [amitraz]
- 26) No direct exposure to [the active ingredient] [amitraz]
- 27) Specially designed for commercial beekeepers
- 28) Easy way to treat your colonies against varroa mites
- 29) No temperature constraint when using Amiflex®, as long as bees are active.
- 30) Amiflex® can be used in any season when the supers are not placed on the hive and as long as bees are active.
- 31) Amiflex® can be introduced as soon as hive activity resumes in the spring, or after the withdrawal of supers, with no temperature constraint, without risk to the colony, as long as bees are active.
- 32) Leave the product inside the hive for 7 days, and then remove.
- 33) Can be used 7 days before a long action treatment to optimize the effectiveness of the long-action treatment
- 34) There are no counter-indications for feeding colonies simultaneously as treating with Amiflex®, as the product does not disturb feeding activity.
- 35) Treat all of your colonies at the same time to avoid re-infestation.
- 36) Respect the dosage. A lower dose can impair the effectiveness.
- 37) Due to its quick action, the product can be used several times (twice per year maximum) during the year to limit the exponential growth of mites.
- 38) Remove the product at the end of treatment in order to prevent the presence of low quantities of amitraz in the hive and prevent the development of possible resistance.
- 39) Reduced waste
- 40) Unique packaging specially designed for commercial beekeepers

Additional claims

- 41) When used according to label directions, Amiflex® does not harm the bees, beekeepers, or hive products thanks to its components quality and specific dosage.
- 42) Honey and wax samples tested after Amiflex® treatments were below the maximum residue limit (MRL) (0.1ppm in honey) for amitraz.
- 43) Specifically formulated for beehives.
- 44) [Not harmful] [No negative effect] to brood, bees, and queens when used according to the label directions.
- 45) No brood mortality induced by Amiflex® at the recommended dose.
- 46) Allows high flexibility in timing varroa treatments during the season due to a short treatment period and flash action [knockdown effect].

Distribution Statements

- 47) Available from your beekeeping supplier

- 48) Convenient and economical
- 49) Ideal for [commercial beekeepers] [large apiaries]