

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

APIFOR bee-hive solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:

Formic acid 600 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Bee-hive solution.

Transparent colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees (*Apis mellifera*)

4.2 Indications for use, specifying the target species

Treatment of varroosis caused by *Varroa destructor* in honey bees (*Apis mellifera*)

4.3 Contraindications

Do not use at daily temperatures outside the specified range (10-30°C)

4.4 Special warnings for each target species

Use according to local treatment recommendations, if available.

Colonies require adequate ventilation during treatment.

All colonies in the same apiary should be treated simultaneously to avoid robbing.

The product should only be used as part of an Integrated Varroa Management program.

It is highly recommended to monitor phoretic mite levels monthly during periods of brood rearing and treat when local thresholds are reached.

To ensure sufficient efficacy the product should be used when outdoor temperatures exceed 10°C.

4.5 Special precautions for use

Special precautions for use in animals

Do not treat with honey supers. Do not disturb the hives for minimum 10 days during the treatment.

Temperatures: to ensure a good efficacy of the product the ideal range of external temperatures during the treatment should be 10-30°C. Temperatures above 30°C during the early three days of treatment may cause excessive brood mortality and queen loss. Treatment should be postponed until temperatures drop. Colonies require adequate access to fresh air during the treatment. The hive entrance needs to be fully open all through the treatment (min. 10 days). Entrance reducers must be removed to prevent damage to colonies.

To avoid an intolerable formic acid concentration, it is essential to ensure sufficient ventilation over the entire treatment period. Do not destroy queen cells that may be observed prior to or after the treatment. Supercedure, even if thought to be set in motion by treatment, is a natural process, and should be allowed to proceed for the health of the colony. Verify the colony is queen-right one month after treatment. Mother and daughter queens present post treatment are not uncommon. Bearding behavior may be observed. Colonies should have good food reserves at time of treatment, should not be fed during treatment. Check the food reserves after the end of treatment and if needed add food.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.

The product is a transparent colourless liquid, very volatile, strongly corrosive, with a pungent smell. Formic acid may cause hypersensitivity (allergy). People with known hypersensitivity to formic acid should avoid contact with the veterinary medicinal product.

This veterinary medicinal product is irritating to the skin, eyes and the respiratory tract. Avoid contact with the skin, eyes and mucous membranes and inhalation of vapours.

Personal protective equipment consisting of protective clothing (EN 14605), chemical resistant gloves (EN 374), safety goggles (EN 166) and mask with a filter (EN 14387) should be worn when handling the veterinary medicinal product. Remove heavily contaminated clothes as soon as possible and wash before re-use. In case of accidental spillage onto skin, wash the affected areas immediately with running water. In case of accidental spillage into the eyes, rinse immediately with clear running water for 10 minutes.

In case of accidental inhalation move to fresh air. If irritation persists after any type of exposure, seek medical advice and show the package leaflet or the label to the physician.

Keep children well away during the application of the product. In case of accidental ingestion immediately rinse mouth and drink plenty of water, but DO NOT induce vomiting.

Do not eat, drink or smoke whilst handling and applying the product.

Wash hands with soap and water directly after use.

Others precautions

This product is corrosive. Avoid contact with metal surfaces.

4.6 Adverse reactions (frequency and seriousness)

Formic acid can disturb colony activity and may result in queen rejection or slight increase of worker bees mortality within one day after application. In the initial stage of the treatment, brood mortality may occur. After the treatment period, colony conditions return to normal.

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interactions with other medicinal products and other forms of interaction

Do not use simultaneously with other acaricides.

4.9 Amounts to be administered and administration route

In hive use, the product must be used as follows:

Recommended dosage for beehive volume: 2.0 - 2.5 g formic acid per litre beehive volume, equal to 3.8-4.8 mL of product/L of beehive volume. The recommended dose must be adjusted to the volume of the beehive used. For example for Dadant hive (about 60 L up to 90 L of volume with the supper) the total dosage to be used is 228-288 ml per beehive (342-432 ml per beehive with supper).

The total amount of product per hive should be adjusted depending on the level of infestation, the colony strength and the external conditions (temperature and humidity).

Method and duration of treatment: the product is introduced into the beehive with the aid of suitable dispensers (evaporators). The particularity of this application consists in the continuous and constant evaporation of small doses per unit time over a prolonged period. The evaporation of the formic acid into the colony must occur with the maximum possible regularity for a minimum period of 10 days until complete evaporation of the product. The dispenser is removed when no more formic acid is present in the reservoir/container. It is recommended to use suitable applicators/evaporators which must be placed in the upper part of the volume of the beehive, in order to ensure a better diffusion of the vapours and that are specifically developed for formic acid evaporation with a wick and a patented evaporation system that allows a slow release of the acid solution (*e.g.* B.L.V. Formic, Nassenheider Professional).

To use horizontal dispensers, it is necessary to place empty honey supers on the colonies. This results in increased volume and dosage of the hive.

Hive type / Volume (L) per single box	
Langstroth (one body) / 44L	Dadant / 60L
Lusitana and Reversível / 54L	AZ hive / 76L

Integrated Varroa Management

The efficacy may vary between colonies due to the conditions of use (environmental factors related to the site and climatic conditions, temperature, genetics and level of infestation, reinfestation, numbers of bees,

strength of the colony, size of the brood, bee mortality etc.). The product should therefore be used as a treatment amongst others within an Integrated Varroa Management program, and mite drop should be regularly monitored.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose extract the evaporator and reduce the surface of evaporation. The use of higher dose than recommended could lead to excessive brood loss, adult bee mortality, queen loss, and/or absconding. In case of overdose, increase hive ventilation by creating additional entrances from top to bottom. Check the presence of queen 2 weeks after application.

4.11 Withdrawal period

Honey: Zero days

Do not use during the honey flow.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutical group: Ectoparasiticides, insecticides and repellents, organic acid, formic acid
ATCvet Code QP53AG01

5.1 Pharmacodynamic properties

Formic acid from the product acts by fumigation, or vapour action.

Formic acid is active against mites on adult bees and is known to kill mites and their offspring within capped brood cells.

The mode of action of formic acid has not been fully elucidated. The available data show an inhibition of the mitochondrial respiratory chain and acidosis of body tissues. *Varroa destructor* is more susceptible for this mechanism than the bee, this explains the therapeutic selectivity.

5.2 Pharmacokinetic particulars

The pharmacokinetics of formic acid in honeybees has not been studied.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicine as packaged for sale: 4 years.

Shelf-life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

Protect from direct sunlight.

Store in a dry place.

Store in the original container, tightly closed in a well-ventilated area, away from sulphuric acid, strong oxidizing agents (e.g. nitric acid, peroxides, perchlorates, chlorites) and sources of ignition.

6.5 Nature and composition of immediate packaging

Packaging:

High density polyethylene Bottle (HDPE) opaque white with High density polyethylene screw cap

High density polyethylene container (HDPE) opaque white with High density polyethylene screw cap

Bottle of 1L

Container of 5L

On the surface of each container, inscriptions necessary to identify the medicine are shown.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

The product should not be allowed to contaminate watercourses, as this may be dangerous for fish and other aquatic organisms. Not to be disposed of with household waste.

7. MARKETING AUTHORISATION HOLDER

CHEMICALS LAIF S.P.A.

V.le dell'Artigianato n° 13, 35010 Vigonza (PD), Italia

8. MARKETING AUTHORISATION NUMBER

MA n°

9. DATE OF THE FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLYING AND/OR USE

Not applicable

DISTRIBUTION PATTERN OF DRUG

The sale is not only reserved to the chemist's and the product does not need to be sold by veterinary prescription.

**PACKAGE LEAFLET AND LABELLING FOR:
APIFOR bee-hive solution.**

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder and manufacturer responsible for batch release:

CHEMICALS LAIF S.P.A.
Viale dell'Artigianato 13
35010 Vigonza (PD), Italy

2. Name of the veterinary medicinal product

APIFOR bee-hive solution

3. Statement of the active substance (s) and other ingredients

Each gram contains:

Active substances:

Formic acid 600 mg

Excipients:

Purified water

4. Pharmaceutical form

Bee-hive solution.

Transparent colourless liquid.

5. Package size

Bottle of 1L

Container of 5L

6. Indication(s)

Treatment of varroosis caused by *Varroa destructor* in honey bees (*Apis mellifera*)

7. Contraindications

Do not use at daily temperatures outside the specified range (10-30°C)

8. Adverse reactions

Formic acid can disturb colony activity and may result in queen rejection or slight increase of worker bees mortality within one day after application. In the initial stage of the treatment, brood mortality may occur. After the treatment period, colony conditions return to normal.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Honey bees (*Apis mellifera*)

10. Dosage for each species, route(s) and method of administration

In hive use, the product must be used as follows:

Recommended dosage for beehive volume: 2.0 - 2.5 g formic acid per litre beehive volume, equal to 3.8-4.8 mL of product/L of beehive volume. The recommended dose must be adjusted to the volume of the beehive used. For example for Dadant hive (about 60 L up to 90 L of volume with the supper) the total dosage to be used is 228-288 ml per beehive (342-432 ml per beehive with supper).

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11. Advice on correct administration

Not Applicable

12. Withdrawal period(s)

Honey: Zero days

Do not use during the honey flow.

13. Special storage precautions

Protect from direct sunlight.

Store in a dry place.

Store in the original container, tightly closed in a well-ventilated area, away from sulphuric acid, strong oxidizing agents (e.g. nitric acid, peroxides, perchlorates, chlorites) and sources of ignition.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP

The expiry date refers to the last day of that month.

14. Special warning(s)

Special warnings for each target species:

Use according to local treatment recommendations, if available.

Colonies require adequate ventilation during treatment.

All colonies in the same apiary should be treated simultaneously to avoid robbing.

The product should only be used as part of an Integrated Varroa Management program.

It is highly recommended to monitor phoretic mite levels monthly during periods of brood rearing and treat when local thresholds are reached.

To ensure sufficient efficacy the product should be used when outdoor temperatures exceed 10°C.

Special precautions for use in animals:

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Temperatures: to ensure a good efficacy of the product the ideal range of external temperatures during the treatment should be 10-30°C. Temperatures above 30°C during the early three days of treatment may cause excessive brood mortality and queen loss. Treatment should be postponed until temperatures drop. Colonies require adequate access to fresh air during the treatment. The hive entrance needs to be fully open all through the treatment (min. 10 days). Entrance reducers must be removed to prevent damage to colonies.

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Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The product is a transparent colourless liquid, very volatile, strongly corrosive, with a pungent smell. Formic acid may cause hypersensitivity (allergy). People with known hypersensitivity to formic acid should avoid contact with the veterinary medicinal product.

This veterinary medicinal product is irritating to the skin, eyes and the respiratory tract. Avoid contact with the skin, eyes and mucous membranes and inhalation of vapours.

Personal protective equipment consisting of protective clothing (EN 14605), chemical resistant gloves (EN 374), safety goggles (EN 166) and mask with a filter (EN 14387) should be worn when handling the veterinary medicinal product. Remove heavily contaminated clothes as soon as possible and wash before re-use. In case of accidental spillage onto skin, wash the affected areas immediately with running water. In case of accidental spillage into the eyes, rinse immediately with clear running water for 10 minutes.

In case of accidental inhalation move to fresh air. If irritation persists after any type of exposure, seek medical advice and show the package leaflet or the label to the physician.

Keep children well away during the application of the product. In case of accidental ingestion immediately rinse mouth and drink plenty of water, but DO NOT induce vomiting.

Do not eat, drink or smoke whilst handling and applying the product.

Wash hands with soap and water directly after use.

This product is corrosive. Avoid contact with metal surfaces.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other acaricides.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose extract the evaporator and reduce the surface of evaporation. The use of higher dose than recommended could lead to excessive brood loss, adult bee mortality, queen loss, and/or absconding. In case of overdose, increase hive ventilation by creating additional entrances from top to bottom. Check the presence of queen 2 weeks after application.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

15. Special precautions for the disposal of unused product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

The product should not be allowed to contaminate watercourses, as this may be dangerous for fish and other aquatic organisms. Not to be disposed of with household waste.

16. Date on which the label was last approved

<DD/MM/YYYY>

17. Other information

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

For animal treatment only.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP: {month/year}

Shelf life after first opening the container: 3 months

21. Marketing authorisation number(s)

...

22. Manufacturer's batch number

<Batch> <Lot> <BN> {number}