

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apilife Var bee-hive strip for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bee-hive strip contains:

Active substances:

| | |
|------------------|--------|
| Thymol | 8,00 g |
| Eucalyptus oil | 1,72 g |
| Camphor, racemic | 0,39 g |
| Levomenthol | 0,39 g |

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Bee-hive strip

Green foam sponge, approximately 7.5 x 5.0 x 0.5 cm, impregnated with essential oils

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees (*Apis mellifera*)

4.2 Indications for use, specifying the target species

Bees (*Apis mellifera*)

Treatment of varroosis caused by *Varroa destructor*.

4.3 Contraindications

Do not use during honey flow in order to avoid tainting the taste of the honey.

Do not use when maximum daytime temperature is above 30°C.

4.4 Special warnings

Treatment at temperatures above of 30°C lead to increased stress and mortality of adult bees and brood.

For maximum efficacy use the product in late summer after the honey harvest, when the amount of bee brood present is diminishing.

The ideal outside temperature for a good effectiveness of the product during the treatment ranges between 20-25°C. Insufficient efficacy can be expected if the average outside temperature is lower than 15°C

4.5 Special precautions for use

Special precautions for use in animals

Do the treatments without supers. Do not perform during honey flow but after the relative honey harvest.

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

Avoid disturbance to the hive. Do not place the strip in the centre of the beehive or near the brood.

Never place strips near a sugar feeder as this may reduce feeding.

It is not recommended to treat hives in cold weather.

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

Because of possible contact dermatitis and irritation of the skin and eyes observed with thymol, direct skin and eye contact should be avoided.

When handling the product, wear impermeable gloves as well as the usual protection equipment.

After application, wash hands and the material being in contact with the strip with soap and water.

In case of skin contact, wash thoroughly the affected area with soap and water.

In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water and seek medical advice.

Do not inhale

4.6 Adverse reactions (frequency and seriousness)

Bees may remove food from directly under the strip.

Treatment at temperatures above of 30°C may lead to increased stress and mortality of adult bees and brood.

The colony may become slightly agitated during treatment.

There may be reduced acceptance of the food if feeding at the same time as treatment.

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 Posology and method of administration

Dosage: 1 strip every 7 days for each beehive, complete treatment 4 strips for each beehive. The treatment should be done once per year.

Application: to perform the treatment take one strip from the sachet and place it in one of the four corners above the honeycombs, far away from the brood placed in the center of the beehive. Close the beehive and let the product work for 7 days

The strip can also be used by cutting it into 3-4 pieces to be placed in the corners of the beehive (see Figures 1;2;3;4). Repeat the treatment for 4 consecutive times. At the end of the treatment, the pieces of strips still present must be removed.

It is not recommended to use the product in multiple storey hives as unsatisfactory efficacy might be expected.



Fig. 1 Open the proper bag that contains the two strips.



Fig. 2 Take one of the two strips and break it into 3-4 parts

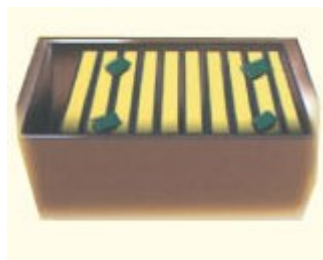


Fig. 3 Open the hive and set the single pieces of the strip to the corners on the lath holding the comb.



Fig. 4 Close the hive and let the product act for 7 days. Repeat the explained treatment for 4 times with the other strips and remove the possible pieces of strip at the end of the treatment.

Integrated Pest Management

The efficacy may vary between colonies due to the surrounding conditions (temperature, reinfestation etc.). The product should therefore be used as a treatment amongst others within an Integrated Pest Management program, and mite drop regularly monitored. Colonies with an average mite drop of more than 1 mite per day two weeks right after the last treatment have to be subjected to an additional winter or spring treatment for varroa (preferably with another active ingredient).

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

In the case of an overdose of too many strips, bees can be disturbed, showing increased stress and a change in behaviour. They exit the beehive and remain outside. If dead bees and grubs are found, remove excess strips.

4.11 Withdrawal period

Honey: Zero days

Do not use during honey flow in order to avoid to adulterate the taste of the honey

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutical group:

Provisional ATCvet Code n° QP53AX30 (combinations of other ectoparasiticides for topical use)

5.1 Pharmacodynamic properties

APILIFE VAR is composed of a mixture of essential oils (thymol, camphor, menthol and eucalyptol), of which the main component is thymol. This mixture of essential oils sublimate inside the air volume of the treated beehive, according to the temperature. This mixture of vapours is released inside the beehive.

Their exact mode of action is not understood. Almost certainly, they act directly on the mites through inhalation and contact. This results in the mites coming off the bees.

5.2 Pharmacokinetic particulars

The pharmacokinetics of the active substances of Apilife Var in bees are not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Foamed phenolic resin (5 cm x 7,5 cm x 0,5 cm)

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

Shelf-life of the veterinary medicine as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: All bee-hive strips in an opened sachet should be used immediately.

6.4 Special storage precautions

Store below 25°C.

Do not refrigerate or freeze.

Protect sachets from direct sunlight.

Protect from frost

Store the strip in the original packaging.

6.5 Nature and composition of immediate packaging

Sachets formed of a polyester/paper-polyethylene/aluminium/polypropylene laminate contain two bee-hive strips, each weighing approximately 11 g

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 water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

CHEMICALS LAIF S.P.A.

V.le dell'Artigianato n° 13, 35010

Vigonza (PD), Italy

Tel. (049) 626281 – Fax (049) 628501

8. MARKETING AUTHORISATION NUMBER

A.I.C. n° 103132015

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

Date of the first authorisation: 01/01/2001

Date of the renewal of the authorisation: 16/09/2005

10. DATE OF REVISION OF THE TEXT

January 2013

PROHIBITION OF SALE, SUPPLYING AND/OR USE

Not pertinent

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/LABELLING FOR:
APILIFE VAR bee-hive strip for honey bees**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
CHEMICALS LAIF S.P.A.**

V.le dell'Artigianato n° 13, 35010 Vigonza (PD), Italy
Tel. +39 049 626281 – Fax +39 049 628501 e-mail: info@chemicalslaif.it

**NAME AND ADDRESS OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE
CHEMICALS LAIF S.P.A.**

Via Roma n° 69, 36020 Castegnero (VI), Italy
Tel. +39 0444 730289 – Fax +39 0444 730295; e-mail: info@chemicalslaif.it

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

APILIFE VAR bee-hive strip for honey bees

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each bee-hive strip contains:

Active substances: Thymol 8,00 g; Eucalyptus oil 1,72 g; Camphor racemic 0,39 g;
Levomenthol 0,39 g;

Excipients: foamed phenolic resin.

4. INDICATION(S)

Treatment of varroosis of the bees caused by Varroa destructor.

5. CONTRAINDICATIONS

Do not use during honey flow in order to avoid tainting the taste of the honey.

Do not use when maximum daytime temperature is above 30°C.

6. ADVERSE REACTIONS

Bees may remove food from directly under the strip.

Treatment at temperatures above 30°C may lead to increased stress and mortality of adult bees and brood.

The colony may become slightly agitated during treatment.

There may be reduced acceptance of the food if feeding at the same time as treatment.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Bees (*Apis mellifera*)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage: 1 strip every 7 days for each beehive, complete treatment 4 strips for each beehive. The treatment should be done once per year.

Application: to perform the treatment take one strip from the sachet and place it in one of the four corners above the honeycombs, far away from the brood placed in the centre of the beehive. Close the beehive and let the product work for 7 days.

The strip can also be used by cutting it into 3-4 pieces to be placed in the corners of the beehive. Repeat the treatment for 4 consecutive times. At the end of the treatment, the pieces of strips still present must be removed.

It is not recommended to use the product in multiple storey hives as unsatisfactory efficacy might be expected.

9. ADVICE ON CORRECT ADMINISTRATION

Not Applicable

10. WITHDRAWAL PERIOD

Honey: Zero days

Do not use during honey flow in order to avoid to adulterate the taste of the honey

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store below 25°C.

Do not refrigerate or freeze.

Protect sachets from direct sunlight.

Protect from frost

Store the strip in the original packaging.

12. SPECIAL WARNINGS

Treatment at temperatures above 30°C lead to increased stress and mortality of adult bees and brood. For maximum efficacy use the product in late summer after the honey harvest, when the amount of bee brood present is diminishing. The ideal outside temperature for a good effectiveness of the product during the treatment ranges between 20-25°C. Insufficient efficacy can be expected if the average outside temperature is lower than 15°C. Do the treatments without supers. Do not perform during honey flow but after the relative honey harvest. All colonies in the same apiary should be treated simultaneously to avoid robbery. Avoid disturbance to the hive. Do not place the strip in the center of the beehive or near the brood. Never place strips near a sugar feeder as this may reduce feeding. It is not recommended to treat hives in cold weather.

Because of possible contact dermatitis and irritation of the skin and eyes observed with thymol, direct skin and eye contact should be avoided.

When handling the product, wear impermeable gloves as well as the usual protection equipment. After application, wash hands and the material being in contact with the strip with soap and water. In case of skin contact, wash thoroughly the affected area with soap and water. In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water and seek medical advice. Do not inhale

Do not use simultaneously with other acaricides.

In the case of an overdose of too many strips, bees can be disturbed, showing increased stress and a change in behaviour. They exit the beehive and remain outside. If dead bees and grubs are found, remove excess strips.

13. 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 water courses as this may be dangerous for fish and other aquatic organisms.

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2013

16. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the marketing authorisation holder

17. MANUFACTURER'S BATCH NUMBER

Batch n.:

18. EXPIRY DATE

Expiry Date:

After first opening of the sachet all strips should be used immediately.

Marketing authorisation number:

Packaging size: sachet containing 2 strips