PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

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

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

Manufacturer responsible for batch release:
CHEMIFARMA SPA
Via Don Eugenio Servadei 16,
47122 Forlì (FC), Italy

2. Name of the veterinary medicinal product

API-Bioxal 886 mg/g powder for in-hive use.
Oxalic acid dihydrate.

3. Statement of the active substance and other ingredients

Each g contains:
Active substance:
Oxalic acid dihydrate 886 mg (equivalent to 632.70 mg of Oxalic acid)

4. Pharmaceutical form

Powder for in-hive use.
White fine powder.

5. Package size

35 g
175 g
350 g

6. Indication

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

7. Contraindications

None.

8. Adverse reactions

Slightly agitation was very commonly observed during treatment with the product.
Increased adult bee mortality was very commonly observed after treatment with the product.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 colonies treated displaying adverse reaction(s))
- common (more than 1 but less than 10 colonies in 100 colonies treated)
- uncommon (more than 1 but less than 10 colonies in 1,000 colonies treated)
- rare (more than 1 but less than 10 colonies in 10,000 colonies treated)
- very rare (less than 1 animal in 10,000 colonies treated, including isolated reports).

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:
A) Posology and method of administration by trickling:
The dosage required is 5 ml per seam (gap between top bars of frames) of bees. Maximal dose is 50 ml per hive. Up to two treatments per year (winter and/or spring-summer season in brood-free colonies).
The treatment should be made in a single administration. The product should be administered using a syringe along the length of each seam of bees. To prepare the solution, open the sachet wearing proper protective mask, gloves and glasses. Pour all the powder in the indicated amount of syrup (water and sucrose in a 1:1 ratio) and mix until dissolution. Concentration of the solution: 4,2% w/v oxalic acid in 60% w/v sucrose syrup (i.e. one bag of 35 g in 500 ml sucrose syrup that is constituted with 308 ml of water and 308 g of sucrose)".
- Sachet 35g: dissolve in 500 ml of syrup (treatment for around 10 beehives).
- Sachet 175g: dissolve in 2.5 l of syrup (treatment for around 50 beehives).
- Sachet 350g: dissolve in 5.0 l of syrup (treatment for around 100 beehives).

B) Posology and method of administration by vaporization:
Dose is 2.3g per hive as a single administration. Maximal dose 2.3g per hive as a single administration. One treatment per year. Use an electric resistance device for vaporisation. It is recommended to follow manufacturer's instructions in order to achieve maximum sublimation. Fill the pan of the vaporizer with 2.3 g of the product. Place the appliance through the entrance of the hive under the bees, avoiding contact with the honey combs. Seal the entrance of the hive to avoid escape of the bees and smoke. Turn on the vaporizer following the manufacturer's instructions for about 3 minutes and keep the hive shut for another 15 minutes. Cool down and clean the vaporizer after use to remove possible residue (max 6%, around 0.140 g). Use drinkable water for cooling and/or cleaning.

11. Advice on correct administration

Integrated Pest Management Programme: the efficacy may vary between colonies due to the conditions of use (residue presence of brood, temperature, reinfestations etc.). The product should therefore be used as a treatment amongst others within an Integrated Pest Management program, and mite drop regularly monitored.

12. Withdrawal period

Withdrawal period
Honey: Zero days.
Do not use in colonies with supers or during honey flow.

13. Special storage precautions

Do not refrigerate or freeze. Store in the original package. Keep the original package tightly closed in order to protect from light and moisture. Store away from foodstuffs.
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 warnings

Special warnings for each target species: for greatest efficacy, the product should only be used when the quantity of brood in the colony is non-existent or at its lowest levels. Oxalic acid does not penetrate wax so will not kill mites within capped brood and therefore the presence of brood may noticeably reduce the efficacy of the product. As such, the product should be used in winter or following manipulation of the colony to produce a broodless state in summer (e.g. by queen caging). With regard to summer treatments following queen caging, highest levels of efficacy were achieved when a caging period of at least 25 days was used, at which point the colonies were completely broodless. Despite proper treatment, seriously damaged colonies may not survive due to the effects of varroa infestation.

Special precautions for use in animals: administer the treatment without supers. All colonies in the same apiary should be treated simultaneously to avoid reinfestations. Avoid disturbance to the hives during the days after the treatment. Use of the sublimation method of administration is not recommended in summer.

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

The product may be irritant to the skin, eyes and respiratory tract, or cause contact dermatitis. Avoid direct contact and inhalation of the product.
When handling the powder (both during vaporisation and pre-treatment phases) wear a protective mask conforming to European standard EN149 (type FFP2), gloves and protective glasses.
After application, wash hands and any skin that comes into contact with the product with soap and water. Thoroughly wash any clothing that comes into contact with the product.
In case of eye contact, wash the eyes thoroughly with large amounts of clean running water and seek medical advice.

Do not inhale. In case of accidental inhalation, breathe fresh air; if you have difficulty breathing, seek medical advice and show the physician this warning.
In case of ingestion, do not induce vomiting, but seek medical advice and show the physician this warning. Do not eat, drink or smoke while handling the product.
Keep out of the sight and reach of children.

Interaction with other medicinal products and other forms of interaction: do not use simultaneously with other **acaricides.**

Overdose (symptoms, emergency procedures, antidotes), if necessary: significantly higher bee mortality was observed in hives that received double (by sublimation) or triple (by trickling) dosages of product. In addition, when overdosed, the over-wintering capacity of colonies was diminished and there may be detrimental effects on colony development in the future.

Incompatibilities: in the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

June 2021

17. Other information

Multilayer polyester-Aluminium-Polyethylene laminated bags, heat sealed, containing 35 g, 175 g and 350 g of powder.
Pack sizes:
1 x 35 g of powder
1 x 175 g of powder
1 x 350 g of powder
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact 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.
Shelf life after reconstitution according to directions: 24 hours.

21. Marketing authorisation number(s)

Vm 23101/4001

22. Manufacturer's batch number

<Batch:><Lot:> {number}

Approved: 02/08/21