PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet Multilayer polyester-Aluminium-Polyethylene laminated bags

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Api-Bioxal 632.7 mg/g bee-hive powder

2. COMPOSITION

Each g contains:
Active substance:
632.7 mg oxalic acid equivalent to 886.0 mg of oxalic acid dihydrate

Excipients:
Silica, colloidal hydrate; Glucose monohydrate;
White fine powder.

3. PACKAGE SIZE

35 g
175 g
350 g

4. TARGET SPECIES

Honey bees (*Apis mellifera*)

5. INDICATIONS FOR USE

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

6. CONTRAINDICATIONS

None.

7. SPECIAL WARNINGS

For greatest efficacy, the veterinary medicinal 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 veterinary medicinal product. As such, the veterinary medicinal 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 safe use in the target species: 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 veterinary medicinal product may be irritant to the skin, eyes and respiratory tract, or cause contact dermatitis. Avoid contact with the skin, eyes, mucous membranes and inhalation. Personal protective equipment consisting of protective mask conforming to European standard EN149 (type FFP2), protective gloves and protective glasses should be worn when handling the veterinary medicinal product (both during vaporisation and pre-treatment phases). After application, wash hands and any skin that comes into contact with the veterinary medicinal product with soap and water. Thoroughly wash any clothing that comes into contact with the veterinary medicinal 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 veterinary medicinal product.

Special precautions for the protection of the environment:
The veterinary medicinal product should not enter water courses as oxalic acid may be dangerous for fish and other aquatic organisms.

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

Overdose: significantly higher bee mortality was observed in hives that received double (by sublimation) or triple (by trickling) dosages of veterinary medicinal 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.

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

8. ADVERSE EVENTS

Honey bees:

Very common (>1 colony/ 10 colonies treated):	Bee systemic disorder (Slight agitation of colony during treatment; Increased adult bee mortality rate after treatment)

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system at: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

In-hive use, the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

10. 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 veterinary medicinal product should therefore be used as a treatment amongst others within an Integrated Pest Management program, and mite drop regularly monitored.

11. WITHDRAWAL PERIODS

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

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate or freeze.
Store in the original package.
Keep the container 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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater. This veterinary medicinal product should not enter water courses as oxalic acid may be dangerous for fish and other aquatic organisms. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 23101/4001

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.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:
Chemicals Laif S.P.A
Viale dell'Artigianato 13,
35010 Vigonza (PD), Italy
info@chemicalslaif.it

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

Local representative and contact details to report suspected adverse reactions:
EH Thorne (Beehives) Ltd.
Beehive Business Park
Rand, Market Rasen
LN8 5NJ, Wragby
Telephone: 01678 858555

18. OTHER INFORMATION

<Other information>

AVM-GSL

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the container: 3 months.
Shelf life after reconstitution according to directions: 24 hours.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 20 February 2025