MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet

500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
API-Bioxal 44.2 mg/ml bee-hive solution.
Oxalic acid.

2. COMPOSITION
Each ml contains:

Active substance:

Oxalic acid	44.2 mg
(as oxalic acid dihydrate	62.0 mg)

Bee-hive solution. Clear colourless-light yellow liquid.

Excipients:
Glycerol
Water, purified.

3. PACKAGE SIZE
500 ml bottle

4. TARGET SPECIES
Honeybees (*Apis mellifera*).

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

6. CONTRAINDICATIONS
None.

7. 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.
All colonies in the same apiary should be treated simultaneously to avoid reinfestations.

Special precautions for use in animals:
Administer the treatment without supers. Avoid disturbance to the hives during the days after the treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product is a highly acidic solution that may cause severe irritation to the skin and eyes. Avoid contact with the skin, eyes and mucous membranes. When handling the product wear protective clothing, chemical-resistant gloves, and safety glasses. After application, wash hands with soap and water and thoroughly wash any clothing that comes into contact with the product. In case of accidental spillage onto the skin, wash the affected areas immediately with running water. In case of accidental eye contacts, flush the eyes immediately with clear running water for 10 minutes.
Accidental ingestion may cause severe adverse reactions. Children should not come into contact with this veterinary medicinal product. In case of accidental ingestion, clean mouth with water and drink plenty of water or milk. Do not induce vomiting. Seek medical advice immediately.
Do not eat, drink or smoke while handling the product.

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

Overdose (symptoms, emergency procedures, antidotes):
Significantly higher bee mortality was observed in hives that received by trickling a triple 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 used simultaneously with other veterinary medicines.

8. ADVERSE REACTIONS

Target species: Honey bees (*Apis mellifera*)

Very common (>1 colony/10 colonies treated):	Slight agitation(during treatment) Increased adult bee mortality (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 using the contact details on this label, or via your national reporting system (Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine e-mail: adverse.events@vmd.gov.uk)

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

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

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.

10. ADVICE ON CORRECT ADMINISTRATION

Integrated Pest Management Program
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.

11. WITHDRAWAL PERIOD

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

12. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Store in the original package
Keep the container tightly closed in order to protect from moisture. Do not use this veterinary medicinal product after the expiry date which is stated on the label.
EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container 12 months.
Once the container is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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

API-Bioxal should not be allowed to contaminate water courses as this may be dangerous for fish and other aquatic organisms. The product should not be disposed of via wastewater.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

AVM-GSL

Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 23101/5000

Pack sizes:
1 x 500 mL bottle
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

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

17. CONTACT DETAILS

Marketing authorisation holder:
CHEMICALS LAIF S.p.A.,
Viale dell'Artigianato 13,
35010 Vigonza (PD), Italy.
Tel. +39049626281
Email. info@chemicalslaif.it

Manufacturer responsible for batch release:
CHEMIFARMA S.p.A.,
Via Don Eugenio Servadei 16,
47122 Forlì (FC), Italy.

18. OTHER INFORMATION

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

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 12 months

21. BATCH NUMBER

Lot:

22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

Approved 12 July 2023