Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

API-Bioxal 62 mg/ml bee-hive solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxalic acid dihydrate 62.0 mg
(equivalent to 44.2 mg of anhydrous oxalic acid)

Excipients:
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Bee-hive solution.
Clear colourless-light yellow 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

None.

4.4 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.

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

4.5 Special precautions for use

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.

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

- The product may be irritant to the skin and eyes, or cause contact dermatitis. Avoid contact with the skin, eyes and mucous membranes.
- When handling the product wear protective 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.
- 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.

4.6 Adverse reactions (frequency and seriousness)

Slight 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).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

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:

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.

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

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.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, Incl. insecticides, organic acids, oxalic acid.
ATC vet code: QP53AG03.

5.1 Pharmacodynamic properties

Oxalic acid is an Organic acid. Oxalic acid is highly effective against phoretic varroa mites. Studies on the mode of action of oxalic acid have indicated that its low pH is a major contributor to the acaricidal effect. Oxalic acid has been shown to concentrate on mite legs and the edges of the exoskeleton, but none was detected in the alimentary system of mites. Therefore, mites are thought to receive the acid by contact.

5.2 Pharmacokinetic particulars

Oxalic acid, the active ingredient of the product, is a natural honey constituent and its concentration in honey depends on the botanical source. No increase of oxalic acid residues over the natural content of honey is to be expected as a consequence of proper product administration. After product treatments, oxalic acid distributes into the intestine and haemolymph of honeybees where its concentration rises temporarily.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Water, purified.

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 medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 12 months

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

- 500 ml bottle: White opaque high-density polyethylene bottles with child – resistant screw cap (HDPE) and tamper-evident seal;
- 5 l container: white opaque high-density polyethylene cans, with screw cap (HDPE) and tamper-evident seal;
- 5 l bag-in-box container: opaque low-density polyethylene container in a cardboard box, bag-in-box (Ecopack) with screw cap (HDPE) and tamper-evident seal;

Available in pack sizes of 1 x 500 mL bottle; 1 x 5-litre HDPE container and 1 x 5-litre LDPE container.
Not all pack sizes may be marketed.

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

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 household waste.

7 MARKETING AUTHORISATION HOLDER

Chemicals Laif S.P.A
Viale dell'Artigianato 13 - Vigonza (PD)
35010
Italy

8 MARKETING AUTHORISATION NUMBER(S)

VPA10388/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 December 2021

10 DATE OF REVISION OF THE TEXT