SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Api-Bioxal 632.7 mg/g bee-hive powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

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

Excipients:

Qualitative composition of excipients and other constituents
Silica, colloidal hydrate
Glucose monohydrate

White fine powder.

3. CLINICAL INFORMATION

3.1 Target species

Honey bees (*Apis mellifera*).

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 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.

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.

3.5 Special precautions for use

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.

3.6 Adverse events

Honey bees:

Very common (>1 colony/ 10 colonies treated):	Bee systemic disorder [1;2;]

[1] Slight agitation of colony during treatment
[2] Increased adult bee mortality rate after treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national

competent authority via the national reporting system. See also the combined label and package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with other acaricides.

3.9 Administration routes and dosage

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 vaporisation
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AG03

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Oxalic acid, the active ingredient of the veterinary medicinal 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 veterinary medicinal product administration. After veterinary medicinal product treatments, oxalic acid distributes into the intestine and haemolymph of honeybees where its concentration rises temporarily.
When 4.2% oxalic acid (in 60% sucrose syrup) was administered by trickling, peak contamination of worker bees occurred within 4 days post-treatment, declining to 9% and 2% of the maximum value at 7 and 11 days post-treatment, respectively. Oxalic acid was detected in the alimentary system and haemolymph of bees. Administration of oxalic acid by sublimation resulted in lower intestinal levels and a faster decline of total levels compared to trickling.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

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

Shelf life after reconstitution according to directions: 24 hours

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

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.

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

Medicines should not be disposed of via wastewater.
The 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chemicals Laif S.P.A

7. MARKETING AUTHORISATION NUMBER

Vm 23101/4001

8. DATE OF FIRST AUTHORISATION

8 September 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

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

Gavin Hall
Approved: 20 February 2025