

PACKAGE LEAFLET/LABELLING FOR:

API-Bioxal

886 mg/g soluble powder for honey-bees

1. MARKETING AUTHORISATION HOLDER

CHEMICALS LAIF s.r.l.

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MANUFACTURER AND RESPONSIBLE FOR BATCH RELEASE

CHEMIFARMA SPA

Via Don Eugenio Servadei n° 16, 47100 Forlì (FC), Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

API-Bioxal, 886 mg/g soluble powder for honey-bees

Oxalic acid dihydrate

3. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g of product contains:

Active substances:

Oxalic acid dihydrate 88,60 g

Excipients: qb a 100,0 g.

4. INDICATIONS FOR USE

Treatment of varroosis (*Varroa destructor*, parasite of *Apis mellifera*).

5. CONTRAINDICATIONS

The product was used only in broodless period or further to a man-made stop of brood. The presence of brood may be reduce noticeably the efficacy of API-Bioxal.

6. ADVERSE REACTIONS

The colony may become slightly agitated during treatment. If you notice any serious effects or other effects not mentioned in this leaflet, please inform a veterinary surgeon.

7. TARGET SPECIES

Honey bees (*Apis mellifera*)

8. POSOLOGY AND METHOD OF ADMINISTRATION

The product is a soluble powder for honey-bees and must be used as follow:

A) Posology and method of administration by trickling:

Open the sachet of API-Bioxal and dissolve all the powder in the indicated amount of syrup (water and sucrose in a 1:1 ratio).

- API-Bioxal sachet 35g: dissolve in 500 ml of syrup.
- API-Bioxal sachet 175g: dissolve in 2.5 l of syrup.
- API-Bioxal sachet 350g: dissolve in 5.0 l of syrup.

The treatment should be made in a single administration, dropping the solution with a syringe on the honey-combs, across their direction, in dose of 5 ml per honey-comb full of bees.

B) Posology and method of administration by vaporisation

Use an electric resistance device for vaporisation. Fill with 2.3 g of API-Bioxal the pan of the vaporizer. Place the appliance through the entrance of the hive under the bees and to avoid the contact with the honey combs. Seal the entrance of the hive to avoid escape of bees and smoke. To power the vaporizer following the manufacturer's directions for about 3 minutes (about 280-290°C of final temperature) and Keep the hive shut for another 10 minutes.

Cool down and clean the vaporizer after every use form possible residue (max 6%, around 0,140 g). Use drinkable water for cooling and/or cleaning.

9. ADVICE ON CORRECT ADMINISTRATION

Not Applicable

10. WITHDRAWAL PERIOD

Honey: Zero days

11. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze. Protect sachets from direct sunlight. Store the powder in the original packaging. Close properly the bag after its opening in order to protect the medicine from humidity

12. SPECIAL WARNINGS

Special warnings for each target species

To obtain a higher efficacy, use the product in colonies naturally without brood or man-made broodless. Despite proper treatments, colonies seriously damaged could not survive to infestation effects.

Special precautions for use

Special precautions for use in animals

Do the treatments without supers. All colonies in the same apiary should be treated simultaneously to avoid reinfestations. Avoid disturbance to the hives the days after the treatment.

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

Because of possible contact dermatitis and irritation of the skin and eyes observed caused to pH of the product, direct skin and eye contact should be avoided. When handling the product (both treatment phase and post-treatment-phase), wear impermeable gloves and protective glasses. When handling powder product (both during vaporisation phase and pre-treatment phases) wear protective mask type FFP2, gloves and protective glasses. After application, wash hands and the material being in contact with the strip with soap and water. In case of skin contact, wash thoroughly the affected area with soap and water. In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water and seek medical advice. Do not inhale.

Interactions with other medicinal products and other forms of interaction

Do not use simultaneously with other acaricides.

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

Possible overdose can trouble the future colonies development. Especially, overdoses or continuous administrations may produce, in the colonies, a decrease of adult-bees number.

Incompatibilities

Do not use simultaneously with other acaricides for compatibility studies absence.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS.

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

The product should not be allowed to contaminate water courses as this may be dangerous for fish and other aquatic organisms.

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

THE SALE IS UNDER NO-REPEAT VETERINARY PRESCRIPTION IN SINGLE COPY.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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16. OTHER INFORMATION

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

17. MANUFACTURER’S BATCH NUMBER

Batch n.:

18. EXPIRY DATE

Expiry Date:

After first opening of the sachet all strips should be used within 03 months

Marketing authorisation number: SEE spc

Packaging size:

- API-Bioxal sachet of 35g
- API-Bioxal sachet of 175g
- API-Bioxal sachet of 350g