

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varroaxal 1 g/g bee-hive powder for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance: 1 g oxalic acid dihydrate (equivalent to 0.71 g oxalic acid).

White, crystalline powder.

3. CLINICAL INFORMATION

3.1 Target species

Honey bee (*Apis mellifera*)

3.2 Indications for use for each target species

Treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

3.3 Contraindications

None.

3.4 Special warnings

Use only in brood-free colonies due to a lack of efficacy on Varroa inside brood cells. Treatments should be carried out at times of the day when bees are not flying. The summer treatments of swarms, artificial swarms or man-made broodless colonies must be followed by an autumn/winter or spring treatment against Varroa.

The efficacy may vary between colonies due to the conditions of use (temperature, reinfestations etc.). Use the product as part of an Integrated Pest Management program with regular mite monitoring. Using different substances during the year reduces the risk of building resistance.

The application of high amounts of oxalic acid could lead to higher bee mortality; therefore, exact dosing is necessary.

Evaporation/sublimation application: To be used in the broodless colony as a single treatment in autumn/winter at outdoor temperatures between 2°C and 10°C. A second evaporation treatment after a 2-week interval is only recommended for:

- Heavily reinfested colonies with a remaining infestation of over 6%.
- Colonies where patches of sealed brood cells are present during wintertime.

Trickling application: To be used in the broodless colony in summer after the honey harvest or in autumn/winter as a single treatment at outdoor temperatures above - 15°C.

Spraying application: To be used in swarms, artificial swarms or man-made broodless colonies as a single treatment in spring/summer or in autumn/winter at outdoor temperatures above 8°C. A second spraying treatment after a 2-week interval is only recommended for heavily reinfested colonies with a remaining infestation of over 6%.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid disturbance to the hives for several days after treatment.

If bees are treated more than once per generation of worker bees, it can result in damage to the bees and a reduction in strength of the colony.

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

This product is highly acidic and corrosive and could cause severe irritation of eyes, oral and respiratory mucosa, irritation of the skin, and contact dermatitis. Inhalation may cause nosebleeds, headaches, and/or vomiting. Avoid inhalation, accidental ingestion and skin and eye contact including hand-to-mouth and hand-to-eye contact. Children should not come in contact with this product. Keep children away when preparing and administering this product. Beware of bystanders. Avoid all direct contact with the product during preparation, use, cleaning, and disposal. Personal protective equipment consisting of chemical resistant gloves, an FFP3 mask, and safety glasses should be worn when handling and applying the product. During preparation, handle the product outdoors or in well-ventilated areas. When spraying and evaporating, apply product with your back to the wind. Remove contaminated clothing immediately and wash before re-use. Do not eat, drink or smoke during handling of the product. Used measuring devices and empty containers should be thoroughly washed and/or disposed of immediately and not left in the sight and reach of children.

In case of accidental ingestion, rinse mouth with water and drink plenty of water or milk. Do not induce vomiting. In case of accidental inhalation, move to fresh air and rest in a position comfortable for breathing. In case of skin or eye contact, immediately rinse thoroughly with water and remove contaminated clothing or contact lenses. If skin/eye irritation persists, or if the product has been inhaled or ingested, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Corrosion sensitive materials should be prevented from contact with oxalic acid dihydrate solutions.

Caking of the product may occur, these agglomerations/lumps may be physically broken down with a spoon. Caking may result in increased dissolution time.

3.6 Adverse events

Target species: Honey bee

Very common (>1 colony / 10 colonies treated):	Increased bee mortality rate ¹
Common (1 to 10 colonies / 100 colonies treated):	Agitation of colony ²
Undetermined frequency (cannot be estimated from the available data):	Hive weakness ³

¹ with the trickling or spraying treatment.

² during treatment.

³ in spring with the trickling 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 the national competent authority via the national reporting system. See the 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

For in-hive use.

*One evenly filled, flat measuring spoon contains 1 g oxalic acid dihydrate. Caking of the product may occur, these agglomerations/lumps may be physically broken down with a spoon. Caking may result in increased dissolution time.

Evaporation/sublimation application:

Place **2 spoonfuls*** of the product into a suitable device (e.g. Varrox or Varrox Eddy vaporizer) for evaporation to treat one colony. Follow the instructions of the evaporation device. Keep hive entrance closed after the treatment for some time to prevent bees from exiting the hive.

Trickling application:

- *For winter treatments in Northern and Central Europe: Mix **8 spoonfuls*** of the product with **200 ml of lukewarm sugar syrup 1:1** (30 to 35°C) in a non-metallic container to obtain a 4% (m/V) oxalic acid dihydrate solution*

(which corresponds to a 2.8% (m/V) oxalic acid solution) to treat four colonies.

- *For summer treatments in all of Europe:* Mix **12 spoonfuls*** of the product with **200 ml of lukewarm sugar syrup 1:1** in a non-metallic container to obtain a 6% (m/V) oxalic acid dihydrate solution (which corresponds to a 4.2% (m/V) oxalic acid solution) to treat four colonies.

Close the container and shake vigorously until the oxalic acid dihydrate powder is completely dissolved. Wait until the solution is clear. The trickling solution is now ready to use and should be applied lukewarm.

Fill a syringe (60 ml) or similar device with the needed amount of ready-to-use solution to treat a colony. The dose per comb side is 0.25 ml/dm².

	Amounts of ready-to-use trickling solution per row of brood frames
Small frames (DNM, National, Simplex, WBC, Zander)	3-4 ml
Large frames (Dadant, Swiss Hive)	5-6 ml

For two storey hives, trickle first the lower brood chamber and then the upper brood chamber.

Spraying application:

Mix **6 spoonfuls*** of the product with **200 ml of lukewarm tap water** in a hand sprayer to obtain a 3% (m/V) oxalic acid dihydrate solution (which corresponds to a 2.1% (m/V) oxalic acid solution) to treat three colonies.

Close the hand sprayer and shake. The solution is now ready to use. Spray 2-4 ml of the solution over each side of the comb that are covered by bees. If only half of the frame is covered with bees the dosage must be reduced by 50%. The maximum dose is 80 ml per hive. The total volume required varies with the hive system:

- Man-made broodless colonies or swarms newly lodged in hives should be treated with a dose of 0.3 ml/dm² of comb fully covered with bees and for the most common hives as follows:

Hive system	Amounts of ready-to-use spraying solution per brood frame side covered with bees
DNM, National, Simplex, WBC, Zander	2 - 3 ml
Commercial beehive, Langstroth, Swiss hive	2.5 - 3.5 ml
AZ-hive (SI), Dadant	3 - 4 ml

- Swarms, artificial swarms in the cluster should be sprayed with 20-25 ml of the ready-to-use spraying solution per kg of bees.

For an accurate dosage spray with your hand sprayer 10 times into a measuring cup and calculate the volume for one pump action. Calculate how many pump actions are required to treat one side of a frame. The combs should be sprayed at a 45° inclination in order to minimize the direct spraying into the cells.

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

In Northern/Central Europe, one autumn/winter treatment with a dose of up to 4.6% (m/V) oxalic acid dihydrate and in summer one dose of up to 6.2% is tolerated well. A significantly higher dose than recommended can lead to bee loss in excess of natural levels and to a poor survival of the colony in spring. Repeated treatments on the same generation of worker bees can lead to increased bee mortality a negative effect on brood development and queen loss.

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. The product should not be used during honey flow. Administer the treatment without honey supers mounted.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 53 AG 03

4.2 Pharmacodynamics

Oxalic acid acts as a contact poison on phoretic *Varroa destructor* mites. The oxalic acid dihydrate solution is spread topically by physical contact between the bees. The mode of action is not fully understood but it is assumed that the low pH-value of the oxalic acid solution plays an important role.

4.3 Pharmacokinetics

There is evidence that oxalic acid can penetrate the exoskeleton of honey bees. After administration of oxalic acid by trickling, contamination of adult bees was detected at 24 hours, reaching a peak one day later. Steep decreases were observed thereafter, reaching one sixtieth of the peak concentration at 11 days post-treatment. The presence of oxalic acid has been demonstrated in bee haemolymph and the gastrointestinal tract.

The pharmacokinetics of the veterinary medicinal product have not been studied and the information presented is derived solely from scientific literature.

Environmental properties

Oxalic acid dihydrate occurs ubiquitously, has a low hazard profile and degrades very rapidly in the environment.

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.
Contact with calcium-containing solutions can lead to precipitations.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: use within the expiry date.
Shelf life after dissolution according to directions: use immediately.

5.3 Special precautions for storage

Store in the original package. Store in a dry place. Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

HDPE bottle closed with an ALU/HDPE seal and a HDPE/ PP turn and lock cap
packed in a cardboard box with a 1 g measuring spoon. Package sizes: 75 g and 200 g. 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.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Andermatt BioVet GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 36234/5000

8. DATE OF FIRST AUTHORISATION

20 December 2024

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

December 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: 04 February 2025