# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard/Box}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains: 1 g oxalic acid dihydrate (equivalent to 0.71 g oxalic acid)

## 3. PACKAGE SIZE

75 g
200 g

## 4. TARGET SPECIES

Honey bees

## 5. INDICATIONS

For the treatment of varroosis (*Varroa destructor*) on honey bees (*Apis mellifera*) in brood-free colonies.

## 6. ROUTES OF ADMINISTRATION

For in-hive use or topical administration.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Honey: zero days. The product should not be used during honey flow. Administer the treatment without honey supers mounted.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

## 9. SPECIAL STORAGE PRECAUTIONS

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

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Andermatt BioVet GmbH

## 14. MARKETING AUTHORISATION NUMBERS

Vm 36234/5000

## 15. BATCH NUMBER

Lot {number}

# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {HDPE/Bottle}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains: 1 g oxalic acid dihydrate (equivalent to 0.71 g oxalic acid).

## 3. TARGET SPECIES

Honey bees

## 4. ROUTES OF ADMINISTRATION

For in-hive use or topical administration. Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

Withdrawal periods: Honey: zero days. The product should not be used during honey flow. Administer the treatment without honey supers mounted.

## 6. EXPIRY DATE

Exp. {mm/yyyy}

## 7. SPECIAL STORAGE PRECAUTIONS

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

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Andermatt BioVet GmbH

## 9. BATCH NUMBER

Lot {number}

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

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

## 2. Composition

Each gram contains: 1 g oxalic acid dihydrate (equal to 0.71 g oxalic acid).

## 3. Target species

Honey bee (*Apis mellifera*)

## 4. Indications for use

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

## 5. Contraindications

None.

## 6. Special warnings

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%.

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 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.

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.

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

Overdose:
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.

Major incompatibilities:
Do not use simultaneously with other acaricides against varroosis. Contact with calcium-containing solutions can lead to precipitations. Corrosion sensitive materials should be prevented from contact with oxalic acid dihydrate solutions.

## 7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, 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 at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

## 8. Dosage for each species, routes and method of administration

For in-hive use.

*One measuring spoon flat and evenly filled contains 1 g oxalic acid dihydrate.

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/dm$^2$.

| | 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/dm$^2$ 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.

## 9. Advice on correct administration (Do not print heading)

## 10. Withdrawal periods

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

## 11. Special storage precautions

Keep out of the sight and reach of children. Store in the original package. Store in a dry place. Protect from direct sunlight.
Do not use this veterinary medicinal product after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use within the expiry date.
Shelf life after dissolution according to directions: use immediately.

## 12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36234/5000
HDPE bottles closed with an ALU/HDPE seal and a HDPE/ PP turn and lock cap packed in a carboard box with a 1 g measuring spoon.
Package sizes: 75 g and 200 g. Not all pack sizes may be marketed.

## 15. PID link (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

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

## 16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Andermatt BioVet GmbH, Franz-Ehret-Str. 18, 79541 Lörrach, Germany

## 17. Other information

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|---|
| AVM-GSL |

*Gavin Hall*

Approved: 04 February 2025