*[Version 9,03/2022] corr. 11/2022*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varroxal 0.71 g/g bee-hive powder (CZ, DE, EE, EL, ES, FR, HR, HU, LV, LT, NL, PL, PT, SI, SK)
Andermatt Varroxal 0.71 g/g bee-hive powder (AT)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

**Active substance:**

0.71 g oxalic acid (equivalent to 1 g oxalic acid dihydrate)

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 *Varro*a inside brood cells.
Times of increased flight activity, when only a part of the bees can be found on the combs, are less suitable for treatment with oxalic acid. Therefore, especially in the case of a spring/summer treatment, care should be taken that the treatment is carried out at times of the day when the 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*.
Despite proper treatment, seriously damaged colonies may not survive due to prior effects of *Varroa* infestation. 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.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product is highly acidic and could have irritating and corrosive effects on the skin, eyes and mucous membranes.
Avoid direct skin and eye contact, including hand-to-eye contact. Avoid oral exposure, including hand-to-mouth contact. Avoid inhalation.

Wear protective clothing, chemical resistant gloves and safety glasses when handling the product. Wear a protective mask type FFP3 for the evaporation or spraying application and at least type FFP2 for the trickling application. During preparation handle the veterinary medicinal product outdoors or in well-ventilated areas. When evaporating or spraying, apply product with your back to the wind. Beware of bystanders. Do not eat, drink or smoke while handling the product. Used sachets or empty bottles should be disposed of immediately in a proper way. Used equipment should be cleaned after use and stored in a proper way out of the reach of children.
In case of skin or eye contact immediately rinse thoroughly with water and remove contaminated clothing or contact lenses. In case of accidental ingestion, rinse mouth with water and drink water or milk but do not induce vomiting. In case of accidental inhalation, move person to fresh air and keep at rest in a position comfortable for breathing. 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.

Special precautions for the protection of the environment:
None.

Other precautions:
The product is corrosive to metal parts.

### 3.6 Adverse events

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<br>(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 its local representative 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.

| Application method | Number of colonies | Amount of product | Material required |
|---|---|---|---|
| **Evaporation** | 1 | 1 sachet* or | Evaporation device |

| | | | |
|---|---|---|---|
| | | 2 spoonfuls** | |
| **Trickling**<br>(Winter Northern and Central Europe) | 4 | 4 sachets or<br>8 spoonfuls | 200 ml sugar syrup 1:1<br>Non-metallic container<br>Syringe |
| **Trickling**<br>(Winter Southern Europe / Summer) | 4 | 6 sachets or<br>12 spoonfuls | |
| **Spraying** | 3 | 3 sachets or<br>6 spoonfuls | 200 ml tap water<br>Hand sprayer |

* One sachet contains 2 g oxalic acid dihydrate.
** One measuring spoon flat and evenly filled contains 1 g oxalic acid dihydrate.

The veterinary medicinal product should be used as follows:
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% i.e. with more than one mite fall per day.
- Colonies, where patches of sealed brood cells are present during wintertime.

Place the full content of **1 sachet or 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: 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.

- *For the winter treatment in Northern and Central Europe:* Mix the full content of **4 sachets or 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 the winter treatment in Southern Europe or summer treatments in all of Europe:* Mix the full content of **6 sachets** or **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.
The mite drop will continue for 3 weeks.

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%.
Mix the full content of **3 sachets** or **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:

- Broodless colonies, 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. The mite drop will continue for 2 weeks.

### 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. In Southern Europe, one dose of up to 6.2% (m/V) is tolerated well throughout the year.
A higher dose than recommended can lead to an increased bee mortality rate and to a poor survival of the colony in spring.

### 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. Treatment of honey producing hives should be carried out 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 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not use simultaneously with other acaricides against varroosis. 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 (sachet): use immediately.
Shelf life after first opening the immediate packaging (bottle): 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

Sealed paper-PE sachets packed in a PET/ALU/PE bag or HDPE bottle closed with an ALU/HDPE seal and a HDPE/ PP turn and lock cap packed in a carboard box.
Package sizes:

- 10 x 2 g sachets
- 50 x 2 g sachets
- 75 g bottle and 1 g measuring spoon
- 200 g bottle and 1 g measuring spoon

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 or household waste.
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(S)

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

DD/MM/YYYY

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

AT, CZ, DE, EE, ES, FR, HR, HU, LV, LT, NL, PT, SI, SK: Veterinary medicinal product not subject to prescription.
EL, PL: Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

**ANNEX II**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Packet / Box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varroxal 0.71 g/g bee-hive powder (CZ, DE, EE, EL, ES, FR, HR, HU, LV, LT, NL, PL, PT, SI, SK)
Andermatt Varroxal 0.71 g/g bee-hive powder (AT)

## 2. STATEMENT OF ACTIVE SUBSTANCES

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

## 3. PACKAGE SIZE

10 x 2 g
50 x 2 g
75 g
200 g

## 4. TARGET SPECIES

Honey bees

## 5. INDICATIONS

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

## 6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Honey: zero days. The product should not be used during honey flow. Treatment of honey producing hives should be carried out without honey supers mounted.

## 8. EXPIRY DATE

Once dissolved, use immediately.
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

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**{HDPE / Bottle}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varroxal 0.71 g/g bee-hive powder (CZ, DE, EE, EL, ES, FR, HR, HU, LV, LT, NL, PL, PT, SI, SK)
Andermatt Varroxal 0.71 g/g bee-hive powder (AT)

## 2. STATEMENT OF ACTIVE SUBSTANCES

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

## 3. TARGET SPECIES

Honey bees

## 4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

Withdrawal period: Honey: zero days. The product should not be used during honey flow. Treatment of honey producing hives should be carried out without honey supers mounted.

## 6. EXPIRY DATE

Once opened, use within the expiry date. Once dissolved, use immediately.
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}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Paper PE / Sachet**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varroxal 0.71 g/g bee-hive powder (CZ, DE, EE, EL, ES, FR, HR, HU, LV, LT, NL, PL, PT, SI, SK)
Andermatt Varroxal 0.71 g/g bee-hive powder (AT)

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2 g oxalic acid dihydrate

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Once opened, use immediately.
Exp. {mm/yyyy}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Varroxal 0.71 g/g bee-hive powder (CZ, DE, EE, EL, ES, FR, HR, HU, LV, LT, NL, PL, PT, SI, SK)
Andermatt Varroxal 0.71 g/g bee-hive powder (AT)

## 2. Composition

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

## 3. Target species

Honey bees

## 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*. Despite proper treatment, seriously damaged colonies may not survive due to prior effects of *Varroa* infestation.

Special precautions for safe use in the target species:
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 veterinary medicinal product is highly acidic and could have irritating and corrosive effects on the skin, eyes and mucous membranes.
Avoid direct skin and eye contact, including hand-to-eye contact. Avoid oral exposure, including hand-to-mouth contact. Avoid inhalation.
Wear protective clothing, chemical resistant gloves and safety glasses when handling the product. Wear a protective mask type FFP3 for the evaporation or spraying application and at least type FFP2 for the trickling application. During preparation handle the veterinary medicinal product outdoors or in well-ventilated areas. When evaporating or spraying, apply product with your back to the wind. Beware of bystanders. Do not eat, drink or smoke while handling the product. Used sachets or empty bottles should be disposed of immediately in a proper way. Used equipment should be cleaned after use and stored in a proper way out of the reach of children.
In case of skin or eye contact immediately rinse thoroughly with water and remove contaminated clothing or contact lenses. In case of accidental ingestion, rinse mouth with water and drink water or milk but do not induce vomiting. In case of accidental inhalation, move person to fresh air and keep at rest in a position comfortable for breathing. 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.

Other precautions:
The product is corrosive to metal parts.

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

Overdose:
A higher dose than recommended can lead to an increased bee mortality rate and to a poor survival of the colony in spring.

Major incompatibilities:
Do not use simultaneously with other acaricides against varroosis. Contact with calcium-containing solutions can lead to precipitations.

## 7. Adverse events

Honey bee

| |
|---|
| Very common (>1colony/10 colonies treated): |
| Increased bee mortality rate[1] |
| Common (>1 to 10 colonies/100colonies 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.

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

For in-hive use.

| Application method | Number of colonies | Amount of product | Material required |
|---|---|---|---|
| **Evaporation** | 1 | 1 sachet* or 2 spoonfuls** | Evaporation device |
| **Trickling** (Winter Northern and Central Europe) | 4 | 4 sachets or 8 spoonfuls | 200 ml sugar syrup 1:1 Non-metallic container Syringe |
| **Trickling** (Winter Southern Europe / Summer) | 4 | 6 sachets or 12 spoonfuls | |
| **Spraying** | 3 | 3 sachets or 6 spoonfuls | 200 ml tap water Hand sprayer |

* One sachet contains 2 g oxalic acid dihydrate.
** One measuring spoon flat and evenly filled contains 1 g oxalic acid dihydrate.

The veterinary medicinal product should be used as follows:
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% i.e. with more than one mite fall per day.
- Colonies, where patches of sealed brood cells are present during wintertime.

Place the full content of **1 sachet** or **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: 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.

- *For the winter treatment in Northern and Central Europe:* Mix the full content of **4 sachets** or **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 the winter treatment in Southern Europe or summer treatments in all of Europe:* Mix the full content of **6 sachets** or **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.
The mite drop will continue for 3 weeks.

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%.
Mix the full content of **3 sachets** or **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:

- Broodless colonies, 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. The mite drop will continue for 2 weeks.

## 9. Advice on correct administration

## 10. Withdrawal periods

Honey: zero days. The product should not be used during honey flow. Treatment of honey producing hives should be carried out 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 (sachet): use immediately.
Shelf life after first opening the immediate packaging (bottle): 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 or household waste. 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

AT, CZ, DE, EE, ES, FR, HR, HU, LV, LT, NL, PT, SK, SI: Veterinary medicinal product not subject to prescription.
EL, PL: Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Package sizes:
PET/ALU/PE bag with 10 x 2 g or 50 x 2 g sachets
Cardboard box with a 75 g or 200 g bottle and a 1 g measuring spoon.
Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Andermatt BioVet GmbH, Franz-Ehret-Str. 18, 79541 Lörrach, Germany

Local representatives and contact details to report suspected adverse reactions: *To be completed nationally*.

## 17. Other information