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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxuvar 5.7%, 41.0 mg/ml concentrate for solution for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance: Oxalic acid 41.0 mg (equal to 57.4 mg oxalic acid dihydrate)

Excipient:

Qualitative composition of excipients and other constituents
Decalcified water

Achromatic, clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Honey bee (*Apis mellifera*)

3.2 Indications for use for each target species

Treatment of varroosis on honey bees (*Apis mellifera*) due to varroa mites (*Varroa destructor*).

3.3 Contraindications

The veterinary medicinal product must not be used on colonies with brood since it is not effective on varroa which are inside brood cells.

3.4 Special warnings

The efficacy may vary between colonies due to the conditions of use (presence of brood, temperature, reinfestations etc.). The veterinary medicinal product should be used as a treatment within an Integrated Pest Management program with mite drop regularly monitored. The use of different substances for year round treatments is recommended to avoid the risk of resistance.
The **trickling application** must be used in the broodless colony in autumn/winter as a single treatment at outdoor temperatures between –15 °C and 5 °C.
The **spraying application** (autumn/winter or spring/summer) must be used in the broodless colony as a single treatment at outdoor temperatures above 8 °C. A second spraying treatment after a 2-week interval is only recommended for heavily infested colonies with a remaining infestation of over 6% after the first treatment.
The application of high amounts of oxalic acid could lead to higher bee mortality and queen losses; therefore, the exact dosing is necessary.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid disturbance to the hives the days after treatment. If bees are treated more than once per generation, it can result in damage to the bees and a reduction in strength of colony.
The summer treatments of swarms, artificial swarms or man-made broodless colonies must be followed by an autumn or winter treatment against varroa. Do not spray on frames used for honey production in the same season.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product is an acidic solution and could cause severe irritation of the skin, eyes and oral and respiratory mucosa. Avoid all direct contact with the veterinary medicinal product, including accidental ingestion and inhalation of the spray mist. Personal protective equipment consisting of protective clothing, **chemical resistant gloves** and **safety glasses** should be worn. Additionally, a protective **mask type FFP2** should be worn for the spraying application.
In case of accidental ingestion, clean mouth with water and drink afterwards plenty of water or milk. Do not induce vomiting. In case of skin or eye contact immediately rinse thoroughly with water and remove contact lenses. If skin/eye irritation persists, or if the veterinary medicinal 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 veterinary medicinal product is corrosive to metal parts.

3.6 Adverse events

Honey bee:

Undetermined frequency (cannot be estimated from the available data):	Increased bee mortality rate[1] Agitation of colony Hive weakness[2]

[1] with the trickling or spraying treatment.
[2] slight, 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 immediate packaging 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 against varroosis.

3.9 Administration routes and dosage

In-hive use
The veterinary medicinal product must be used as follows:

A) Trickling application
Preparation of the ready-to-use 3.5% (m/V) oxalic acid dihydrate trickling solution:
Pre-warm the oxalic acid dihydrate solution container in a water bath (30–35 °C). Remove it from the water bath and open the sealed container. Add the required amount of sugar (sucrose) as used for feeding the bees:

- **275 g sugar** when using the 275 g bottle
- **1 kg sugar** when using the 1000 g bottle

Close the container and shake vigorously until the sugar is completely dissolved. The solution is now ready to use and should be applied lukewarm.

Administration:
Fill a syringe (60 ml) or similar device through the wide opening of the container with the needed amount of ready-to-use solution to treat a colony. The dose per comb side is 0.25 ml/dm^2 for Western/Central Europe and 0.4 ml/dm^2 for Southern Europe.

Amounts of ready-to-use **trickling** solution per occupied row		
	Western/Central Europe	Southern Europe
Small frames (DNM, National, Simplex, WBC, Zander)	3–4 ml	5–6 ml
Large frames (Dadant, Swiss Hive)	5–6 ml	8–10 ml
Maximum dose per hive	50 ml	80 ml

For two storey hives, trickle first the lower brood chamber and then the upper brood chamber. The mite drop will continue during 3 weeks.
The ready-to-use trickling solution is enough to treat between 6–15 colonies when using the 275 g bottle or between 20–50 colonies when using the 1000 g bottle. The ready-to-use trickling solution has to be used immediately and cannot be stored after preparation.

B) Spraying application
Preparation of the ready-to-use 3% (m/V) oxalic acid dihydrate spraying solution:
Add tap water to the solution:

- **250 g (250 ml) tap water** when using the 275 g bottle
- **900 g (900 ml) tap water** when using the 1000 g bottle

Close the container and shake. The solution is now ready to use.

Administration:
Fill a hand sprayer or similar device with the needed amount of ready-to-use solution. 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 during 3 weeks.
Treat the swarm, artificial swarm or man-made broodless colony in spring/summer as a single treatment when the majority of bees are inside the hive (in the evening).
The ready-to-use spraying solution is enough to treat between 5–10 colonies when using the 275 g bottle or between 25–40 colonies when using the large 1000 g bottle.

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

In Western/Central Europe, one treatment with a dose up to 4.6% (m/V) oxalic acid dihydrate in late autumn is tolerated well. Marginal bee losses are generally compensated by the colony. A significantly higher dose than recommended (higher than 5% (m/V)) can lead to twice the amount of natural bee

loss and to a poor survival of the colony in spring. Repeated treatments within the same season 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 for correctly treated colonies. 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.

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 of the immediate packaging and reconstitution according to directions:

- Trickling application: once reconstituted with sugar: use immediately.
- Spraying application: once reconstituted with tap water use within one year and within the products expiry date.

5.3 Special precautions for storage

Store below 30 °C. Do not refrigerate or freeze. Protect from frost. Store in the original container in an upright position. Keep the bottle tightly closed. Protect from direct sunlight. Discard unused material.

5.4 Nature and composition of immediate packaging

Rigid HDPE container closed with an aluminium seal and a PP child-proof cap.
Pack sizes:
500 ml bottle containing 275 g oxalic acid dihydrate solution.

2000 ml bottle containing 1000 g oxalic acid dihydrate solution.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
The veterinary medicinal product should not enter water courses as this 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(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

SI: Veterinary medicinal product subject to prescription.
AT, BE, CZ, DE, HR, HU, IT, NL, PT, SK: Veterinary medicinal product not subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{HDPE/BOTTLE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxuvar 5.7%, 41.0 mg/ml concentrate for solution for honey bees

2. COMPOSITION

Each ml contains:
Active substance: Oxalic acid 41.0 mg (equal to 57.4 mg oxalic acid dihydrate)
Achromatic, clear concentrate for solution.

3. PACKAGE SIZE

275 g
1000 g

4. TARGET SPECIES

Honey bees

5. INDICATIONS FOR USE

Indications for use
Treatment of varroosis on honey bees (*Apis mellifera*) due to varroa mite (*Varroa destructor*).

6. CONTRAINDICATIONS

Contraindications
The veterinary medicinal product must not be used on colonies with brood since it is not effective on varroa which are inside brood cells.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
The efficacy may vary between colonies due to the conditions of use (presence of brood, temperature, reinfestations etc.). The veterinary medicinal product should be used as a treatment within an Integrated Pest Management program with mite drop regularly monitored. The use of different substances for year round treatments is recommended to avoid the risk of resistance.
The **trickling application** must be used in the broodless colony in autumn/winter as a single treatment at outdoor temperatures between –15 °C and 5 °C.
The **spraying application** (autumn/winter or spring/summer) must be used in the broodless colony as a single treatment at outdoor temperatures above 8 °C. A second spraying treatment after a 2-week interval is only recommended for heavily infested colonies with a remaining infestation of over 6% after the first treatment.
The application of high amounts of oxalic acid could lead to higher bee mortality and queen losses; therefore, the exact dosing is necessary.

Special precautions for safe use in the target species:
Avoid disturbance to the hives the days after treatment. If bees are treated more than once per generation, it can result in damage to the bees and a reduction in strength of colony.
The summer treatments of swarms, artificial swarms or man-made broodless colonies must be followed by an autumn or winter treatment against varroa. Do not spray on frames used for honey production in the same season.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product is an acidic solution and could cause severe irritation of the skin, eyes and oral and respiratory mucosa. Avoid all direct contact with the veterinary medicinal product, including accidental ingestion and inhalation of the spray mist. Personal protective equipment consisting of protective clothing, **chemical resistant gloves** and **safety glasses** should be worn. Additionally, a protective **mask type FFP2** should be worn for the spraying application.
In case of accidental ingestion, clean mouth with water and drink afterwards plenty of water or milk. Do not induce vomiting. In case of skin or eye contact immediately rinse thoroughly with water and remove contact lenses. If skin/eye irritation persists, or if the veterinary medicinal product has been inhaled or ingested, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

The veterinary medicinal product is corrosive to metal parts.

Interactions with other medicinal products and other forms of interaction:
Do not use simultaneously with other acaricides against varroosis.

Overdose:
In Western/Central Europe, one treatment with a dose up to 4.6% (m/V) oxalic acid dihydrate in late autumn is tolerated well. Marginal bee losses are generally compensated by the colony. A significantly higher dose than recommended (higher than 5% (m/V)) can lead to twice the amount of natural bee loss and to a poor survival of the colony in spring. Repeated treatments within the same season 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.

8. ADVERSE EVENTS

Adverse events

Honey bee:

Undetermined frequency (cannot be estimated from the available data):
Increased bee mortality rate[1] Agitation of colony Hive weakness[2]

[1] with the trickling or spraying treatment.
[2] slight, 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 on this label, 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 or its local representative using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
In-hive use

A) Trickling application
Preparation of the ready-to-use 3.5% (m/V) oxalic acid dihydrate trickling solution:
Pre-warm the oxalic acid dihydrate solution container in a water bath (30–35 °C). Remove it from the water bath and open the sealed container. Add the required amount of sugar (sucrose) as used for feeding the bees:

- **275 g sugar** when using the 275 g bottle
- **1 kg sugar** when using the 1000 g bottle

Close the container and shake vigorously until the sugar is completely dissolved. The solution is now ready to use and should be applied lukewarm.
Administration:
Fill a syringe (60 ml) or similar device through the wide opening of the container with the needed amount of ready-to-use solution to treat a colony. The dose per comb side is 0.25 ml/dm^2 for Western/Central Europe and 0.4 ml/dm^2 for Southern Europe.

Amounts of ready-to-use **trickling** solution **per occupied row**		
	Western/Central Europe	Southern Europe
Small frames (DNM, National, Simplex, WBC, Zander)	3–4 ml	5–6 ml
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Maximum dose per hive	50 ml	80 ml

For two storey hives, trickle first the lower brood chamber and then the upper brood chamber. The mite drop will continue during 3 weeks.
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B) Spraying application
Preparation of the ready-to-use 3% (m/V) oxalic acid dihydrate spraying solution:
Add tap water to the solution:

- **250 g (250 ml) tap water** when using the 275 g bottle
- **900 g (900 ml) tap water** when using the 1000 g bottle

Close the container and shake. The solution is now ready to use.
Administration:
Fill a hand sprayer or similar device with the needed amount of ready-to-use solution. 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:

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- 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 during 3 weeks.
Treat the swarm, artificial swarm or man-made broodless colony in spring/summer as a single treatment when the majority of bees are inside the hive (in the evening).
The ready-to-use spraying solution is enough to treat between 5–10 colonies when using the 275 g bottle or between 25–40 colonies when using the large 1000 g bottle.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Withdrawal periods
Honey: zero days for correctly treated colonies. Administer the treatment without honey supers mounted.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions
Keep out of the sight and reach of children.
Store below 30 °C. Do not refrigerate or freeze. Protect from frost. Store in the original container in an upright position. Keep the bottle tightly closed. Protect from direct sunlight. Discard unused material.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
The veterinary medicinal product should not enter water courses as this 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 or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
SI: Veterinary medicinal product subject to prescription.
AT, BE, CZ, DE, HR, HU, IT, NL, PT, SK, UK (NI): Veterinary medicinal product not subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

EU/0/00/000/000

Pack sizes
275 g and 1000 g

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Andermatt BioVet GmbH, Franz-Ehret-Str. 18, 79541 Lörrach, Germany

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, Tel: +49 7621 585 73 10

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

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Trickling application: once reconstituted with sugar use immediately.
Spraying application: once reconstituted with drinking water use within one year and within the products expiry date.
(DE, HR) Once reconstituted, use by _____.

21. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

(All the information is included in the labelling)