ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed 5 mg/ml + 44 mg/ml bee-hive dispersion for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Each ml contains:

Formic acid	5 mg
Oxalic acid dihydrate	44 mg (equivalent to 31.42 mg oxalic acid anhydrous)

Excipients:
Caramel colour (E150d)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee-hive dispersion.
Slightly brown to dark brown aqueous dispersion.

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees

4.2 Indications for use, specifying the target species

Treatment of varroosis (*Varroa destructor*) in honey bee colonies with and without brood.

4.3 Contraindications

Do not use during nectar flow.

4.4 Special warnings for each target species

VarroMed should only be used as part of an integrated Varroa control programme.
Efficacy was only investigated in hives with low to moderate mite infestation rates.

4.5 Special precautions for use

Special precautions for use in animals

Following treatment, worker bees with a protruding proboscis were found. This might be associated with insufficient access to drinking water. Ensure, therefore, that treated bees have sufficient access to drinking water.

The long-term tolerance of VarroMed has only been tested over 18 months, i.e. a negative impact of the product on queens or colony development after longer treatment periods cannot be excluded. It is advised to check regularly that the queen is present, but avoid disturbing the hives in the days following treatment.

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

- This veterinary medicinal product is irritating to the skin and eyes. Avoid contact with the skin, eyes and mucous membranes. In case of accidental spillage onto skin, wash the affected areas immediately with running water. In case of accidental spillage into the eye(s), flush the eye(s) immediately with clear running water for 10 minutes.
- Children should not come into contact with this veterinary medicinal product. Accidental ingestion may cause adverse reactions.
- Personal protective equipment consisting of protective clothing, acid-resistant gloves and glasses should be worn when handling the veterinary medicinal product. Change heavily contaminated clothes as soon as possible and wash before re-use.
- People with known sensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.
- Do not eat, drink or smoke while using the product.

4.6 Adverse reactions (frequency and seriousness)

Increased mortality in worker bees was very commonly observed in the clinical and preclinical trials following treatment with Varromed. This effect is considered to be associated with the oxalic acid in VarroMed, and increased with increasing doses and/or repeated treatments.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 colonies displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 colonies in 100 colonies)
- uncommon (more than 1 but less than 10 colonies in 1,000 colonies)
- rare (more than 1 but less than 10 colonies in 10,000 colonies)
- very rare (less than 1 colonies in 10,000 colonies, including isolated reports.

4.7 Use during pregnancy, lactation or lay

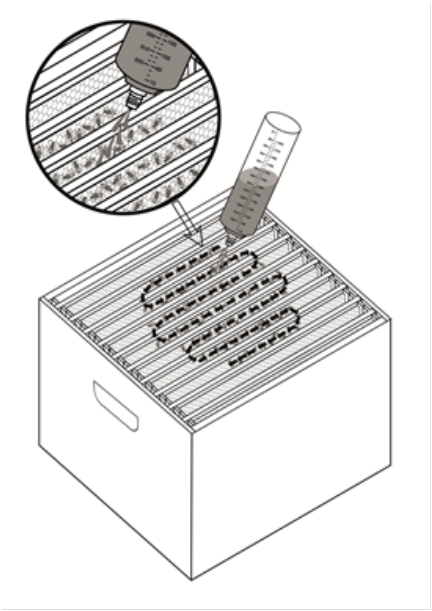
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.
The concomitant use of other acaricidal products should be avoided because increased toxicity to bees might occur.

4.9 Amounts to be administered and administration route

In-hive use.
To be trickled onto bees in occupied bee-spaces of the brood chamber.



Dose:

Shake well before use.

The dose should carefully be adjusted to the colony size (see dosing table). Determine the colony size and number of occupied bee spaces to be treated, and select the correct amount of product required. The following dosing scheme applies:

No. of bees	5,000 - 7,000	7,000 – 12,000	12,000 – 30,000	> 30,000
VarroMed (ml)	15 ml	15 to 30 ml	30 to 45 ml	45 ml

The use of VarroMed with the above dosing scheme only applies for hives with vertical frames that can be accessed from the top, as the treatment of bees in other types of hives has not been investigated.

The multi-dose container has a graduated dosing scale for accurate dosing.

Frequency of treatment:

Repeated administration of VarroMed might be required for spring or autumn treatment at intervals of 6 days, repeated applications should only be performed as indicated by mite-fall in accordance with the following table:

Season	**No. of applications**	**Threshold for first treatment**	**Repeated Treatment:**
Spring	1x or 3x	Treatment should be conducted at the start of the season with increasing colony population and when the natural mite fall is more than 1 mite per day	The treatment should be repeated twice more (that is to a maximum of 3 treatments), if more than 10 mites are detected on the floorboard within 6 days after the first treatment (maximum of 3 treatments).
Autumn	3x	Treatment should be conducted as soon as	The treatment should be repeated twice, 6 days apart (i.e. 3

	up to 5x	possible in late summer/early autumn with decreasing colony population, and when the natural mite fall is more than 4 mites per day.	administrations). The treatment should be repeated twice more (that is to a maximum of 5 treatments), if more than 150 mites (colonies from the second year) or more than 90 mites (nucleus colonies in the first year) are detected on the floorboard within 6 days after the third administration.
Winter (broodless)	1x	Treatment should be conducted at the start of the broodless period in hives with Varroa infestation	Not applicable (single treatment only).

Advice on correct administration
Timing of administration: the product should be used primarily at times when bees have low flight activity (late afternoon, evening). Darkness facilitates distribution of the product between the bees. To avoid overdoses to individual bees, care should be taken to administer VarroMed evenly over the bees, particular in the winter cluster.
VarroMed should not be used during the nectar flow, or when honey chambers are attached to the hive.

Before use, the product should be 25 to 35 °C warm, and then shaken well.

It is recommended to remove the wax bridges between the top bars of the frames before administration of the product.

Do not lift the frames during administration and for approximately one week after the last treatment.

In order to establish the Varroa infestation level in a hive, the mite mortality must be monitored: mite fall should be recorded on the hive floorboard before the first treatment, and up to 6 days after each treatment.

All colonies placed at the same location should be treated at the same time to minimize the risk of re-infestation.

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

Following the administration of a 10% solution of oxalic acid dihydrate in 50% sugar solution, permanent lesions in digestive and excretory organs were noted after 72 hours (h).
Oxalic acid concentrations of 20% in a 50% sugar solution led to acute bee mortalities of more than 60%.

In case of accidental overdose (e.g. spillage of a large quantity of VarroMed into a hive) the best counter measure includes exchanging the hive body and cleaning the frames with water from all visible spills of the dispersion.

4.11 Withdrawal period(s)

Honey: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides, organic acids, combinations

ATCvet code: QP53AG30

5.1 Pharmacodynamic properties

Formic acid probably kills Varroa mites by inhibiting electron transport in their mitochondria through the binding of cytochrome c oxidase, thereby inhibiting energy metabolism and may produce a neuro-excitatory effect on arthropod neurons after evaporation in the hive air (at least 500 ppm). No data are available which confirm this activity after trickling of 0.5% formic acid; however, formic acid in the fixed combination of VarroMed is considered to extend the duration of the effect of oxalic acid, and to improve the tolerance of the product.

The mode of action of oxalic acid against Varroa mites is unknown, but direct contact between the mites and oxalic acid is required. It is assumed that oxalic acid acts via direct contact or by ingestion of oxalic haemolymph. The acaricidal effect may be due mainly to the low pH of the formulation. Oxalic acid treatments administered in water are ineffective, but administration in sugar water improves efficacy by increasing its adhesion to the bees.

5.2 Pharmacokinetic particulars

The pharmacokinetics of VarroMed have not been studied.

However, literature data show that oxalic acid is absorbed to a limited extent after topical application at therapeutic doses under normal beekeeping conditions. Data have also shown that oxalic acid can be orally ingested by bees due to increased self-grooming after dermal application, which might lead to increased toxicity.

The pharmacokinetics of formic acid in bees is not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel colour (E150d)
Sucrose syrup
Propolis tincture 20%
Star anise oil
Lemon oil
Citric acid monohydrate
Purified water

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 30 days.

6.4. Special precautions for storage

Do not store above 25 °C.
Keep the bottle tightly closed.
Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box containing an HDPE bottle with dropper nozzle (LDPE) and screw cap (with tamper evident seal). The bottle has a graduated dosing scale.
Box containing 1 bottle of 555 ml dispersion.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

BeeVital GmbH
Wiesenbergstrasse 19
5164 Seeham
AUSTRIA

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

DD month YYYY

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed 75 mg + 660 mg bee-hive dispersion for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Each single dose sachet contains:

Formic acid	75 mg
Oxalic acid dihydrate	660 mg (equivalent to 471.31 mg oxalic acid anhydrous)

Excipients:
Caramel colour (E150d)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee-hive dispersion.
Slightly brown to dark brown aqueous dispersion.

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees

4.2 Indications for use, specifying the target species

Treatment of varroosis (*Varroa destructor*) in honey bee colonies with and without brood.

4.3 Contraindications

Do not use during nectar flow.

4.4 Special warnings for each target species

VarroMed should only be used as part of an integrated Varroa control programme.
Efficacy was only investigated in hives with low to moderate mite infestation rates.

4.5 Special precautions for use

Special precautions for use in animals

Following treatment, worker bees with a protruding proboscis were found. This might be associated with insufficient access to drinking water. Ensure, therefore, that treated bees have sufficient access to drinking water.

The long-term tolerance of VarroMed has only been tested over 18 months, i.e. a negative impact of the product on queens or colony development after longer treatment periods cannot be excluded. It is advised to check regularly that the queen is present, but avoid disturbing the hives in the days following treatment.

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

- This veterinary medicinal product is irritating to the skin and eyes. Avoid contact with the skin, eyes and mucous membranes. In case of accidental spillage onto skin, wash the affected areas immediately with running water. In case of accidental spillage into the eye(s), flush the eye(s) immediately with clear running water for 10 minutes.
- Children should not come into contact with this veterinary medicinal product. Accidental ingestion may cause adverse reactions.
- Personal protective equipment consisting of protective clothing, acid-resistant gloves and glasses should be worn when handling the veterinary medicinal product. Change heavily contaminated clothes as soon as possible and wash before re-use.
- People with known sensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.
- Do not eat, drink or smoke while using the product.

4.6 Adverse reactions (frequency and seriousness)

Increased mortality in worker bees was very commonly observed in the clinical and preclinical trials following treatment with Varromed. This effect is considered to be associated with the oxalic acid in VarroMed, and increased with increasing doses and/or repeated treatments.

The frequency of adverse reactions is defined using the following convention:
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- rare (more than 1 but less than 10 colonies in 10,000 colonies)
- very rare (less than 1 colonies in 10,000 colonies, including isolated reports.

4.7 Use during pregnancy, lactation or lay

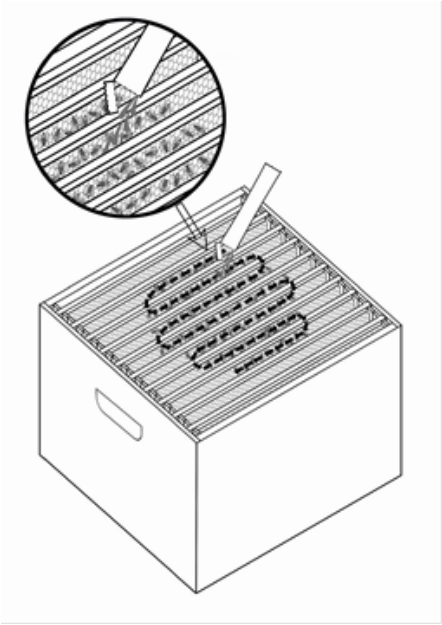
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.
The concomitant use of other acaricidal products should be avoided because increased toxicity to bees might occur.

4.9 Amounts to be administered and administration route

In-hive use.
To be trickled onto bees in occupied bee-spaces of the brood chamber.



Dose:

Shake well before use.

The dose should carefully be adjusted to the colony size (see dosing table). Determine the colony size and number of occupied bee spaces to be treated, and select the correct amount of product required. The following dosing scheme applies:

No. of bees	5,000 - 7,000	7,000 – 12,000	12,000 – 30,000	> 30,000
VarroMed (ml)	15 ml	15 to 30 ml	30 to 45 ml	45 ml

The use of VarroMed with the above dosing scheme only applies for hives with vertical frames that can be accessed from the top, as the treatment of bees in other types of hives has not been investigated.

Frequency of treatment:

Repeated administration of VarroMed might be required for spring or autumn treatment at intervals of 6 days, repeated applications should only be performed as indicated by mite-fall in accordance with the following table:

Season	**No. of applications**	**Threshold for first treatment**	**Repeated Treatment:**
Spring	1x or 3x	Treatment should be conducted at the start of the season with increasing colony population and when the natural mite fall is more than 1 mite per day	The treatment should be repeated twice more (that is to a maximum of 3 treatments), if more than 10 mites are detected on the floorboard within 6 days after the first treatment (maximum of 3 treatments).
Autumn	3x up to 5x	Treatment should be conducted as soon as possible in late summer/early autumn with	The treatment should be repeated twice, 6 days apart (i.e. 3

		decreasing colony population, and when the natural mite fall is more than 4 mites per day.	administrations). The treatment should be repeated twice more (that is to a maximum of 5 treatments), if more than 150 mites (colonies from the second year) or more than 90 mites (nucleus colonies in the first year) are detected on the floorboard within 6 days after the third administration.
Winter (broodless)	1x	Treatment should be conducted at the start of the broodless period in hives with Varroa infestation	Not applicable (single treatment only).

Advice on correct administration
Timing of administration: the product should be used primarily at times when bees have low flight activity (late afternoon, evening). Darkness facilitates distribution of the product between the bees. To avoid overdoses to individual bees, care should be taken to administer VarroMed evenly over the bees, particular in the winter cluster.
VarroMed should not be used during the nectar flow, or when honey chambers are attached to the hive.

Before use, the product should be 25 to 35 °C warm, and then shaken well.

It is recommended to remove the wax bridges between the top bars of the frames before administration of the product.

Do not lift the frames during administration and for approximately one week after the last treatment.

In order to establish the Varroa infestation level in a hive, the mite mortality must be monitored: mite fall should be recorded on the hive floorboard before the first treatment, and up to 6 days after each treatment.

All colonies placed at the same location should be treated at the same time to minimize the risk of re-infestation.

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

Following the administration of a 10% solution of oxalic acid dihydrate in 50% sugar solution, permanent lesions in digestive and excretory organs were noted after 72 hours (h).
Oxalic acid concentrations of 20% in a 50% sugar solution led to acute bee mortalities of more than 60%.

In case of accidental overdose (e.g. spillage of a large quantity of VarroMed into a hive) the best counter measure includes exchanging the hive body and cleaning the frames with water from all visible spills of the dispersion.

4.11 Withdrawal period(s)

Honey: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides, organic acids, combinations

ATCvet code: QP53AG30

5.1 Pharmacodynamic properties

Formic acid probably kills Varroa mites by inhibiting electron transport in their mitochondria through the binding of cytochrome c oxidase, thereby inhibiting energy metabolism and may produce a neuro-excitatory effect on arthropod neurons after evaporation in the hive air (at least 500 ppm). No data are available which confirm this activity after trickling of 0.5% formic acid; however, formic acid in the fixed combination of VarroMed is considered to extend the duration of the effect of oxalic acid, and to improve the tolerance of the product.

The mode of action of oxalic acid against Varroa mites is unknown, but direct contact between the mites and oxalic acid is required. It is assumed that oxalic acid acts via direct contact or by ingestion of oxalic haemolymph. The acaricidal effect may be due mainly to the low pH of the formulation. Oxalic acid treatments administered in water are ineffective, but administration in sugar water improves efficacy by increasing its adhesion to the bees.

5.2 Pharmacokinetic particulars

The pharmacokinetics of VarroMed have not been studied.

However, literature data show that oxalic acid is absorbed to a limited extent after topical application at therapeutic doses under normal beekeeping conditions. Data have also shown that oxalic acid can be orally ingested by bees due to increased self-grooming after dermal application, which might lead to increased toxicity.

The pharmacokinetics of formic acid in bees is not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel colour (E150d)
Sucrose syrup
Propolis tincture 20%
Star anise oil
Lemon oil
Citric acid monohydrate
Purified water

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: use immediately.

6.4. Special precautions for storage

Do not store above 25 °C.
Keep the sachets in the outer carton in order to protect from light.
Opened sachets should not be stored.

6.5 Nature and composition of immediate packaging

Cardboard box containing 12 single-dose sachets (foil PETP/ Al /LDPE), each containing 15 ml dispersion. Sachets are perforated for opening.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

BeeVital GmbH
Wiesenbergstrasse 19
5164 Seeham
AUSTRIA

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

DD month YYYY

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Lichtenheldt GmbH
Industriestr. 7-9
D-23812 Wahlstedt
GERMANY

Labor L+S AG
Mangelsfeld 4-6
D-97708 Bad Bocklet-Grossenbrach
GERMANY

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product not subject to prescription.

C. STATEMENT OF THE MRLs

The active substances in VarroMed, oxalic acid dihydrate and formic acid, are allowed substances as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Oxalic acid	N/A	Bees	No MRL required	N/A	NO ENTRY	Anti-infectious agents
Formic acid	N/A	All food producing species	No MRL required	N/A	NO ENTRY	NO ENTRY

The excipients, listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE
Multi-dose container (bottle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed 5 mg/ml + 44 mg/ml bee-hive dispersion
Formic acid/oxalic acid dihydrate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances:
Formic acid 5 mg/ml
Oxalic acid dihydrate 44 mg/ml

3. PHARMACEUTICAL FORM

Bee-hive dispersion

4. PACKAGE SIZE

555 ml

5. TARGET SPECIES

Honey bees

6. INDICATION(S)

Treatment of varroosis (*Varroa destructor*) in honey bee colonies with and without brood.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-hive use.
Read the package leaflet before use.
Shake well before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Honey: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

During the application of the veterinary medicinal product, wear protective clothing, acid-resistant gloves and glasses.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening container: 30 days
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the bottle tightly closed.
Keep the bottle in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BeeVital GmbH
Wiesenbergstr. 19
A - 5164 Seeham
AUSTRIA

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/203/001-002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 12 sachets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed 75 mg + 660 mg bee-hive dispersion
Formic acid/oxalic acid dihydrate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each sachet contains:
Active substances:
Formic acid 75 mg
Oxalic acid dihydrate 660 mg

3. PHARMACEUTICAL FORM

Bee-hive dispersion

4. PACKAGE SIZE

12 x 15 ml

5. TARGET SPECIES

Honey bees

6. INDICATION(S)

Treatment of varroosis (*Varroa destructor*) in honey bee colonies with and without brood.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-hive use.
Read the package leaflet before use.
Shake well before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Honey: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

During the application of the veterinary medicinal product, wear protective clothing, acid-resistant gloves and glasses.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the sachets in the outer carton in order to protect from light.
Opened sachets should not be stored.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BeeVital GmbH
Wiesenbergstr. 19
A - 5164 Seeham
AUSTRIA

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/203/001-002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
15 ml Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed bee-hive dispersion
Formic acid /oxalic acid dihydrate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Formic acid	75 mg
Oxalic acid dihydrate	660 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 ml

4. ROUTE(S) OF ADMINISTRATION

In-hive use.
Shake well before use.

5. WITHDRAWAL PERIOD

Withdrawal period (honey): zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

VarroMed bee-hive dispersion for honey bees

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder :

BeeVital GmbH
Wiesenbergstr. 19
A - 5164 Seeham
AUSTRIA
+43 6219 20645
+43 6219 20645 30 (fax)
info@beevital.com

Manufacturer responsible for batch release:

Lichtenheldt GmbH
Industriestr. 7-9
D-23812 Wahlstedt
GERMANY
+49-(0)4554-9070-0
+49-(0)4554-9070-901 (fax)
info@lichtenheldt.de

Labor L+S AG
Mangelsfeld 4-6
D-97708 Bad Bocklet-Grossenbrach
GERMANY
+49-(0)9708-9100-0
+49-(0) 9708-9100-36 (fax)
service@labor-ls.de

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed bee-hive dispersion for honey bees
Formic acid / oxalic acid dihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substances:
Each ml contains:

Formic acid	5 mg
Oxalic acid dihydrate	44 mg (equivalent to 31.42 mg oxalic acid)

Excipients:

Caramel colour (E150d)

Slightly brown to dark brown aqueous dispersion.

4. INDICATION(S)

Treatment of varroosis *(Varroa destructor)* in honey bee colonies with and without brood.

5. CONTRAINDICATIONS

Do not use during nectar flow.

6. ADVERSE REACTIONS

Increased mortality in worker bees was very commonly observed in the clinical and preclinical trials following treatment with VarroMed. This effect is considered to be associated with the oxalic acid in VarroMed, and increased with increasing doses and/or repeated treatments.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 colonies displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 colonies in 100 colonies)
- uncommon (more than 1 but less than 10 colonies in 1,000 colonies)
- rare (more than 1 but less than 10 colonies in 10,000 colonies)
- very rare (less than 1 colonies in 10,000 colonies, including isolated reports.

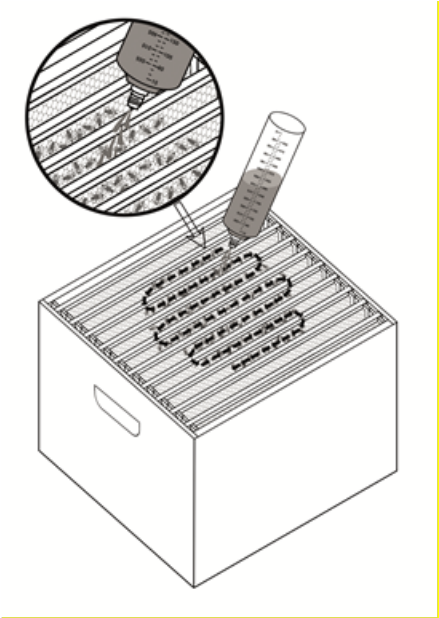
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Honey bees.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In-hive use.
To be trickled onto bees in occupied bee-spaces of the brood chamber.



Dose:
Shake well before use.

The dose should carefully be adjusted to the colony size (see dosing table). Determine the colony size and number of occupied bee spaces to be treated, and select the correct amount of product required.

The following dosing scheme applies:

No. of bees	5,000 - 7,000	7,000 – 12,000	12,000 – 30,000	> 30,000
VarroMed (ml)	15 ml	15 to 30 ml	30 to 45 ml	45 ml

The use of VarroMed with the above dosing scheme only applies for hive types with vertical frames that can be accessed from the top, as the treatment of bees in other types of hives has not been investigated.

The multi-dose container has a graduated dosing scale for accurate dosing.

Frequency of *treatment*:
Repeated administration of VarroMed might be required for spring or autumn treatment at intervals of 6 days; repeated applications should only be performed as indicated by mite-fall in according with the following table:

Season	**No of applications**	**Threshold for first treatment**	**Repeated Treatments:**
Spring	1x or 3x	Treatment should be conducted at the start of the season with increasing colony population and when the natural mite fall is more than 1 mite per day	The treatment should be repeated twice more (that is to a maximum of 3 treatments), if more than 10 mites are detected on the floorboard within 6 days after the first treatment (maximum of 3 treatments).

Autumn –	3x up to 5x	Treatment should be conducted as soon as possible in late summer/early autumn with decreasing colony population, and when the natural mite fall is more than 4 mites per day	The treatment should be repeated twice, 6 days apart (i.e. 3 administrations). The treatment should be repeated twice more (that is to a maximum of 5 treatments), if more than 150 mites (colonies from the second year) or more than 90 mites (nucleus colonies in the first year) are detected on the floorboard within 6 days after the third administration.
Winter (broodless)	1x	Treatment should be conducted at the start of the broodless period in hives with Varroa infestation	Not applicable (single treatment only)

9. ADVICE ON CORRECT ADMINISTRATION

Timing of application: the product should be used primarily at times when bees have low flight activity (late afternoon, evening). Darkness facilitates distribution of the product between the bees.

To avoid overdoses to individual bees, care should be taken to administer VarroMed evenly over the bees, particularly in the winter cluster.
VarroMed should not be used during the nectar flow, or when honey chambers are attached to the hive.

Before use, the product should be 25 to 35 °C warm, and then shaken well.
It is recommended to remove the wax bridges between the top bars of the frames before administration of the product.
Do not lift frames during administration and for approximately one week after the last treatment.

In order to establish the Varroa infestation level in a hive, the mite mortality must be monitored: mite fall should be recorded on the hive floorboard before the first treatment, and up to 6 days after each treatment.
All colonies placed at the same location should be treated at the same time to minimize the risk of re-infestation.
Do not use the veterinary medicinal product if you notice visible signs of deterioration of the product.

10. WITHDRAWAL PERIOD

Honey: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Keep the bottle tightly closed.
Keep the bottle in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date, which is stated on the bottle after "EXP".
Shelf life after first opening the container: 30 days

12. SPECIAL WARNING(S)

Special warnings for each target species
VarroMed should only be used as part of an integrated Varroa control programme.
Efficacy was only investigated in hives with low to moderate mite infestation rates.

Special precautions for use in animals
Following treatment, worker bees with a protruding proboscis were found. This might be associated with insufficient access to drinking water. Ensure, therefore, that treated bees have sufficient access to drinking water.
The long-term tolerance of VarroMed has only been tested over 18 months, i.e. a negative impact of the product on queens or colony development after longer treatment periods cannot be excluded. It is advised to check regularly that the queen is present, but avoid disturbing the hives in the days following treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- The veterinary medicinal product is irritating to skin and eye. Avoid contact with skin, eyes and mucous membranes. In case of accidental spillage onto skin, wash the affected areas immediately with running water. In case of accidental spillage into the eye(s), flush the eye(s) immediately with clear running water for 10 minutes.
- Children should not come into contact with this veterinary medicinal product. Accidental ingestion may cause adverse reactions.
- Personal protective equipment consisting of protective clothing, acid-resistant gloves and glasses should be worn when handling the veterinary medicinal product. Change heavily contaminated clothes as soon as possible and wash before re-use.
- People with known sensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.
- Do not eat, drink or smoke while using the product.

Overdose
Following the administration of a 10% solution of oxalic acid dihydrate in 50% sugar solution, permanent lesions in digestive and excretory organs were noted after 72 hours (h).
Oxalic acid concentrations of 20% in a 50% sugar solution led to acute bee mortalities of more than 60%.

In case of accidental overdose (e.g. spilling of large amounts of VarroMed into a hive) the best counter measure includes exchanging the hive body and cleaning the frames with water from visible spills of the dispersion.

Interaction with other medicinal products and other forms of interaction
None known.
The concomitant use of other acaricidal products should be avoided because increased toxicity to bees might occur.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

VarroMed is available in two pack sizes, multi-dose bottles (1 x 555 ml) and single-dose sachets (12 x 15 ml).
Not all pack sizes may be marketed.

PACKAGE LEAFLET FOR:

VarroMed bee-hive dispersion for honey bees

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder :

BeeVital GmbH
Wiesenbergstr. 19
A - 5164 Seeham
AUSTRIA
+43 6219 20645
+43 6219 20645 30 (fax)
info@beevital.com

Manufacturer responsible for batch release:

Lichtenheldt GmbH
Industriestr. 7-9
D-23812 Wahlstedt
GERMANY
+49-(0)4554-9070-0
+49-(0)4554-9070-901 (fax)
info@lichtenheldt.de

Labor L+S AG
Mangelsfeld 4-6
D-97708 Bad Bocklet-Grossenbrach
GERMANY
+49-(0)9708-9100-0
+49-(0) 9708-9100-36 (fax)
service@labor-ls.de

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VarroMed bee-hive dispersion for honey bees
Formic acid / oxalic acid dihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substances:
Each single dose sachet contains:

Formic acid	75 mg
Oxalic acid dihydrate	660 mg (equivalent to 471.31 mg oxalic acid)

Excipients:
Caramel colour (E150d)

Slightly brown to dark brown aqueous dispersion.

4. INDICATION(S)

Treatment of varroosis *(Varroa destructor)* in honey bee colonies with and without brood.

5. CONTRAINDICATIONS

Do not use during nectar flow.

6. ADVERSE REACTIONS

Increased mortality in worker bees was very commonly observed in the clinical and preclinical trials following treatment with VarroMed. This effect is considered to be associated with the oxalic acid in VarroMed, and increased with increasing doses and/or repeated treatments.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 colonies displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 colonies in 100 colonies)
- uncommon (more than 1 but less than 10 colonies in 1,000 colonies)
- rare (more than 1 but less than 10 colonies in 10,000 colonies)
- very rare (less than 1 colonies in 10,000 colonies, including isolated reports.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Honey bees.

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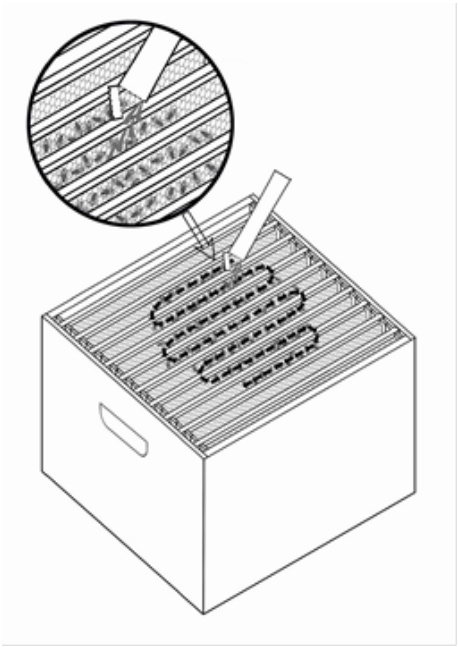

Dose:
Shake well before use.

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VarroMed (ml)	15 ml	15 to 30 ml	30 to 45 ml	45 ml

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Honey: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

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Do not use this veterinary medicinal product after the expiry date, which is stated on the carton after "EXP".
Keep the sachets in the outer carton in order to protect from light.
Opened sachets should not be stored.

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