ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PolyVar Yellow 275 mg bee-hive strip

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bee-hive strip contains:

Active substance:
Flumethrin 275 mg

Excipients:

Qualitative composition of excipients and other constituents
Dibutyl adipate
Propylene glycol dicaprylocaprate
Epoxidised soybean oil
Stearic acid
Polyvinyl chloride
Titanium dioxide (E171)
Iron oxide yellow (E172)

Yellow, plastic strip with 15 holes.

3. CLINICAL INFORMATION

3.1 Target species

Honey bee (*Apis mellifera*).

3.2 Indications for use for each target species

For the treatment of varroosis in honey bees caused by *Varroa destructor* mites.

3.3 Contraindications

Do not use in cases of known resistance against pyrethroids as described in section 3.4, Special warnings.

3.4 Special warnings

The possibility that other colonies located on the same apiary can be a source of re-infestation with *Varroa destructor* should be considered, and these should be treated simultaneously.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each bee hive.

The veterinary medicinal product should be used as part of an integrated *Varroa* control programme.

Resistance to pyrethroids has been reported in *Varroa destructor* in honey bees. According to published literature (2024), the flumethrin resistance among *Varroa destructor* in Turkey ranged from 51% to 94%. Furthermore, widespread resistance to flumethrin globally, highlighting prevalent mutations in Mediterranean countries.

As an effective method to reduce the risk of resistance selection flumethrin containing products – as for other acaricides – should not be used in consecutive years. Instead, strict rotation with products containing active substances from other chemical classes should be applied. Depending on the regional resistance situation a longer treatment break than one year may be necessary. As flumethrin and tau-fluvalinate belong to the same class they are not suitable for rotation with each other. Inappropriate use of the veterinary medicinal product could result in an increased risk of resistance development and could ultimately result in ineffective therapy and colony losses.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. bioassays or molecular analysis (PCR)). In the case of existing resistance to pyrethroids flumethrin containing products should not be applied. Where resistance to pyrethroids has been seen in the past, retesting of the current status of the colony should be considered as reversion to susceptibility can occur over several years. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Flight activity is necessary for exposure to the active substance. In case of prolonged periods of low flight activity, e.g. due to unfavourable weather conditions efficacy may be reduced.

Success of treatment should be monitored with established standard tests like continuous monitoring of natural mite fall using a sticky insert tray, or assessing mite load per 100 bees to determine whether a winter treatment e.g. with oxalic acid is required.

3.5 Special precautions for use

Special precautions for safe use in the target species:

After installation of the veterinary medicinal product, bees may form clusters at the hive entrance for a couple of hours during adjustment.
Adequate ventilation of the hive should be ensured during high temperatures.
The veterinary medicinal product has not been tested during periods of extremely hot weather. The veterinary medicinal product may impact hive ventilation to a similar extent as standard hive entrance reducers and thus should be temporarily removed if considered necessary.

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

Keep the bag with the bee-hive strips in the outer packaging until use.
Open the bag just before using strips.
Wash hands with cold water after fitting the bee-hive strips.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Honey bee (*Apis mellifera*):
None.
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 against varroosis.

3.9 Administration routes and dosage

In-hive use. Use at the bee-hive entrance as a gate.
Use two strips per standard bee-hive.
Underdosing could result in ineffective use and may favour resistance development.

Application of the bee-hive strips:

Treatment should be started within a short time after honey flow and honey extraction to ensure sufficient flight activity for a treatment effect and healthy winter bee development. Treatment should be applied for at least 9 weeks until the end of flight activity but not longer than 4 months. In case of continuous mite fall at 9 weeks treatment should be continued. Thus treatment will usually cover the critical phase of potential horizontal mite transfer, e.g. by robbery. Treatment success should be monitored as mentioned in section 3.4.

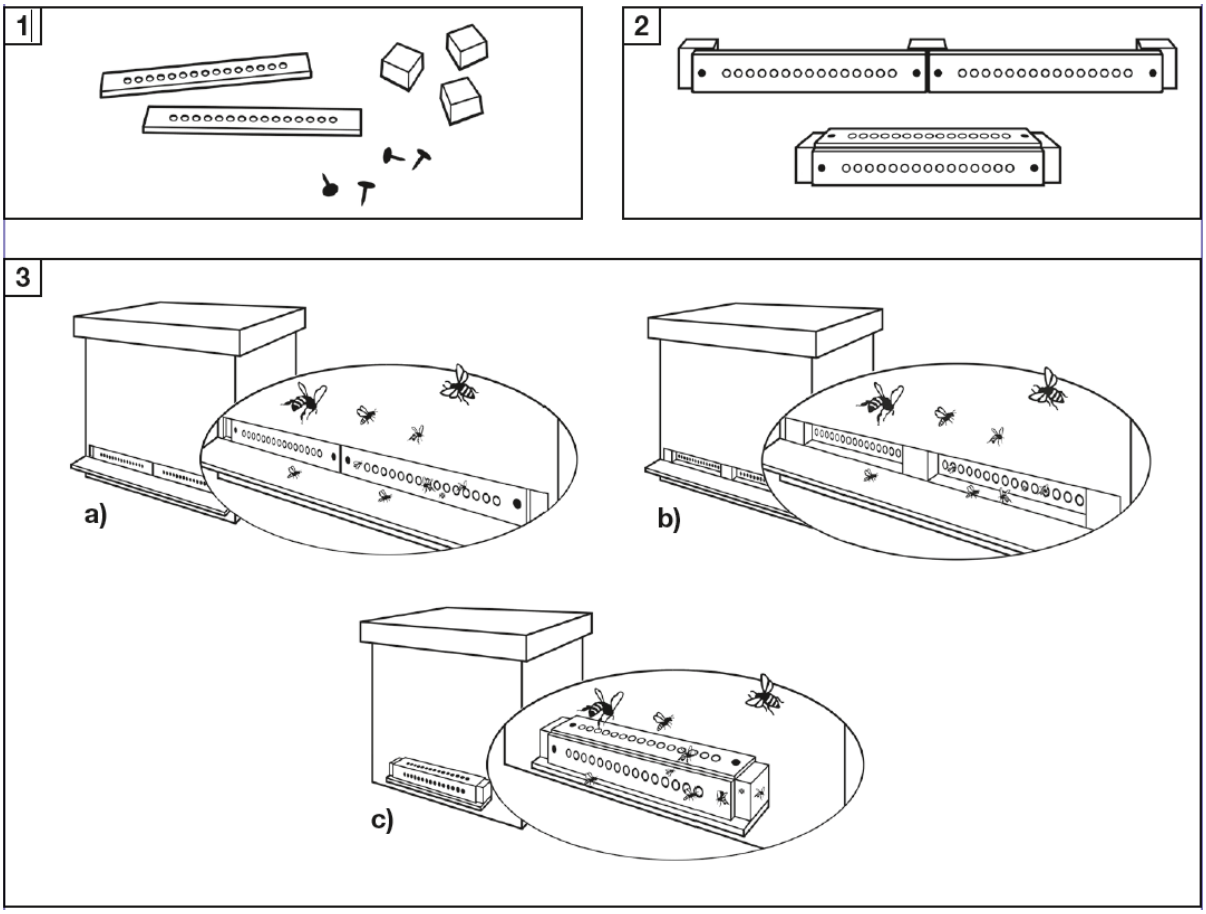
The bee-hive strip should be fitted at the entrance in a way that the bees are forced to enter or leave the hive only through the holes of the strip. The entire surface and the holes of the bee-hive strip should not be covered to ensure the contact of the bees with the strip and to ensure ventilation of the hive. The strips are designed not to impair removal of dead bees. The strips should not be cut.

This pack only contains the bee-hive strips, however, depending on the bee-hive type and the size of the entrance further tools like tacks, staples, nails or blocks of wood may be needed to secure the strip in place. The strips can be fixed in different ways from the inside or outside of the hive.

For hive types with a wide entrance two strips can be fixed inline (see figure 3a, b for e.g. Boczonadi, Dadant, Deutsch normal, Langstroth, Simplex, Spaar-Kast and Zander hives).

For hives with a small entrance the strips can be fixed like a cuboid in front of the entrance (see figure 3c, e.g. Layens, A-Ž hives).

Examples are illustrated below.



Do not re-use bee-hive strip.

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

Due to the nature of the bee-hive strips overdosage is unlikely and signs of overdosage are not to be expected.

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.
Do not use during honey flow.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AC05

4.2 Pharmacodynamics

Flumethrin is an ectoparasiticide of the synthetic pyrethroid group. Synthetic pyrethroids alter the rapid kinetic transitions between conducting (open) and nonconducting (closed or inactivated) states of voltage-gated sodium channels that underlie the generation of nerve action potentials. Thus, they keep sodium channels open for long periods of time, leading to prolonged depolarization of nerve cells, which

is mediated by the α-cyano group on the phenoxy-fluorobenzyl alcohol molecule.. In studies on structure-activity relationship of a number of pyrethroids interference with receptors of a certain chiral conformation was noted thereby causing a selective activity on ectoparasites. No anti-cholinesterase activity was noted with these compounds.
There have been reports of pyrethroid resistance in varroa mites. Some cases have been attributed to alterations in the expression of certain detoxification enzymes, but the most common mechanism of resistance appears to be by mutations at the target receptor, the above-mentioned sodium channel of nerve cell membranes.
In a field study performed using *Varroa destructor*-infested honey bee colonies, the genotypes of post-treatment residual mites (≤5% of the mite population since efficacy was ≥95%) were assessed for the presence of resistance-conferring mutations. Mites with a resistance mutation were detected in approximately 50% of the colonies treated with this veterinary medicinal product and in approximately 64% of colonies treated with another authorised pyrethroid. The mean percentage of homozygous resistant residual mites per colony was approximately 34% in colonies treated with this veterinary medicinal product and 49% in colonies treated with another authorised pyrethroid. Therefore, treatments should be rotated (as explained in section 3.4) in order to prevent further selection for resistance.

4.3 Pharmacokinetics

Bees are exposed to the active substance by direct contact with the gate on entering and leaving the hive and indirectly by social contact inside the hive. There is no evaporation of active substance.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: use immediately. Any remaining veterinary medicinal product should be discarded.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Polyester/aluminium/ low density polyethylene foil bag containing 10 bee-hive strips, packaged into an outer cardboard box.

Pack sizes: cardboard boxes
containing 1 or 10 foil bags

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 flumethrin 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

Elanco

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription. (AT, BE, CZ, DE, EE, IT, LU, NL, SI)
Veterinary medicinal product subject to prescription. (BG, CY, GR, HR, HU, PL, RO, SK)

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 OUTER PACKAGE

{Carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PolyVar Yellow 275 mg bee-hive strip

2. STATEMENT OF ACTIVE SUBSTANCES

Each bee-hive strip contains 275 mg flumethrin.

3. PACKAGE SIZE

10 bee-hive strips
100 bee-hive strips

4. TARGET SPECIES

Honey bees (*Apis mellifera*).

5. INDICATIONS

For products not subject to veterinary prescription:
Treatment of varroosis (*Varroa destructor)*

6. ROUTES OF ADMINISTRATION

In-hive use. Use at the bee-hive entrance as a gate.

7. WITHDRAWAL PERIODS

Withdrawal period for honey: Zero days.
Do not treat during honey flow.

8. EXPIRY DATE

Exp. {month/year}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

[country specific national MA number]

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

{Foil bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PolyVar Yellow 275 mg bee-hive strip

2. STATEMENT OF ACTIVE SUBSTANCES

Each bee-hive strip contains 275 mg flumethrin.

3. TARGET SPECIES

Honey bees (*Apis mellifera*). .

4. ROUTES OF ADMINISTRATION

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

5. WITHDRAWAL PERIODS

Withdrawal period for honey: Zero days.
Do not treat during honey flow.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PolyVar Yellow 275 mg bee-hive strip

2. Composition

Each bee-hive strip contains:

Active substance:
Flumethrin 275 mg

Yellow, plastic strip with 15 holes

3. Target species

Honey bee (*Apis mellifera*).

4. Indications for use

For the treatment of varroosis in honey bees caused by *Varroa destructor* mites.

5. Contraindications

Do not use in cases of known resistance against pyrethroids as described in section 'Special warnings', subsection 'Special warnings'.

6. Special warnings

Special warnings:

The possibility that other colonies located on the same apiary can be a source of re-infestation with *Varroa destructor* should be considered, and these should be treated simultaneously.

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each bee hive.

The veterinary medicinal product should be used as part of an integrated *Varroa* control programme.

Resistance to pyrethroids has been reported in *Varroa destructor* in honey bees. According to published literature (2024), the flumethrin resistance among *Varroa destructor* in Turkey ranged from 51% to 94%. Furthermore, widespread resistance to flumethrin globally, highlighting prevalent mutations in Mediterranean countries.

As an effective method to reduce the risk of resistance selection flumethrin containing products – as for other acaricides – should not be used in consecutive years. Instead, strict rotation with products containing active substances from other chemical classes should be applied. Depending on the regional resistance situation a longer treatment break than one year may be necessary. As flumethrin and tau-fluvalinate belong to the same class they are not suitable for rotation with each other. Inappropriate

use of the veterinary medicinal product could result in an increased risk of resistance development and could ultimately result in ineffective therapy and colony losses.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. bioassays or molecular analysis (PCR)). In the case of existing resistance to pyrethroids flumethrin containing products should not be applied. Where resistance to pyrethroids has been seen in the past, retesting of the current status of the colony should be considered as reversion to susceptibility can occur over several years. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Flight activity is necessary for exposure to the active substance. In case of prolonged periods of low flight activity, e.g. due to unfavourable weather conditions efficacy may be reduced.

Success of treatment should be monitored with established standard tests like continuous monitoring of natural mite fall using a sticky insert tray, or assessing mite load per 100 bees to determine whether a winter treatment e.g. with oxalic acid is required.

Special precautions for safe use in the target species:
After installation of the veterinary medicinal product, bees may form clusters at the hive entrance for a couple of hours during adjustment.
Adequate ventilation of the hive should be ensured during high temperatures.
The veterinary medicinal product has not been tested during periods of extremely hot weather. The veterinary medicinal product may impact hive ventilation to a similar extent as standard hive entrance reducers and thus should be temporarily removed if considered necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Keep the bag with the bee-hive strips in the outer packaging until use.
Open the bag just before using strips.
Wash hands with cold water after fitting the bee-hive strips.

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

Overdose:
Due to the nature of the bee-hive strips overdosage is unlikely and signs of overdosage are not to be expected.

Major incompatibilities:
None known.

7. Adverse events

Target species: Honey bee (*Apis mellifera*).

None.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

In-hive use. Use at the bee-hive entrance as a gate.
Use two strips per standard bee-hive.
Underdosing could result in ineffective use and may favour resistance development.

9. Advice on correct administration

Application of the bee-hive strips:

Treatment should be started within a short time after honey flow and honey extraction to ensure sufficient flight activity for a treatment effect and healthy winter bee development. Treatment should be applied for at least 9 weeks until the end of flight activity but not longer than 4 months. In case of continuous mite fall at 9 weeks treatment should be continued. Thus treatment will usually cover the critical phase of potential horizontal mite transfer, e.g. by robbery. Treatment success should be monitored as mentioned in section 'Special warnings', subsection 'Special warnings'.

The bee-hive strip should be fitted at the entrance in a way that the bees are forced to enter or leave the hive only through the holes of the strip. The entire surface and the holes of the bee-hive strip should not be covered to ensure the contact of the bees with the strip and to ensure ventilation of the hive. The strips are designed not to impair removal of dead bees. The strips should not be cut.

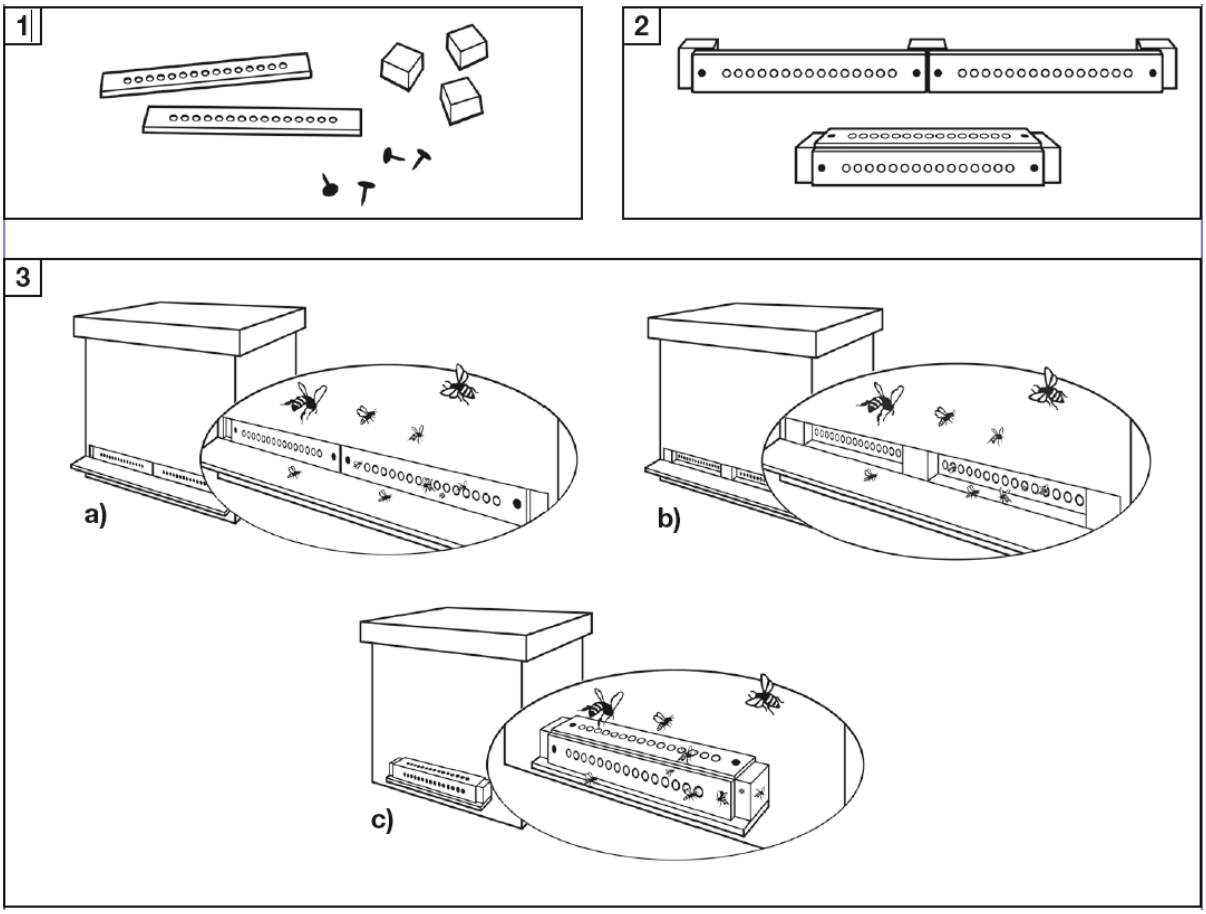
This pack only contains the bee-hive strips, however, depending on the bee-hive type and the size of the entrance further tools like tacks, staples, nails or blocks of wood may be needed to secure the strip in place. The strips can be fixed in different ways from the inside or outside of the hive.

For hive types with a wide entrance two strips can be fixed inline (see figure 3a, b for e.g. Boczonadi, Dadant, Deutsch normal, Langstroth, Simplex, Spaar-Kast and Zander hives).

For hives with a small entrance the strips can be fixed like a cuboid in front of the entrance (see figure 3c, e.g. Layens, A-Ž hives).

For monolingual packaging only:
<Examples are illustrated below. >

For multilingual packaging only:
<Examples are illustrated at the end of the leaflet.>



Do not re-use bee-hive strip.

10. Withdrawal periods

Honey: Zero days.
Do not use during honey flow.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the bag and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately. Any remaining veterinary medicinal product should be discarded.

12. 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 flumethrin 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription. (AT, BE, CZ, DE, EE, IT, LU, NL, SI)
Veterinary medicinal product subject to prescription (BG, CY, GR, HR, HU, PL, RO SK)

14. Marketing authorisation numbers and pack sizes

Polyester/aluminium/ low density polyethylene foil bag containing 10 bee-hive strips, packaged into an outer cardboard box.

Pack sizes: cardboard boxes
containing 1 or 10 foil bags

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{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 and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

Local representatives and contact details to report suspected adverse reactions:

17. Other information

Bees are exposed to the active substance by direct contact with the gate on entering and leaving the hive and indirectly by social contact inside the hive. There is no evaporation of active substance.