ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PolyVar Yellow 275 mg bee-hive strip

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each bee-hive strip contains 275 mg flumethrin.

3. PHARMACEUTICAL FORM

Bee-hive strip

4. PACKAGE SIZE

10 bee-hive strips for the treatment of 5 bee-hives
[100 bee-hive strips for the treatment of 50 bee-hives]

5. TARGET SPECIES

Honey bees

6. INDICATION(S)

Treatment of varroosis (*Varroa destructor)*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Use instructions: Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Special precautions: Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

[not applicable]

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

Disposal: read package leaflet.

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

For animal treatment only.

[country specific prescription status]

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4146

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PolyVar Yellow 275 mg bee-hive strip
flumethrin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each bee-hive strip contains 275 mg flumethrin.

3. PHARMACEUTICAL FORM

Bee-hive strip

4. PACKAGE SIZE

10 bee-hive strips for the treatment of 5 bee-hives
[100 bee-hive strips for the treatment of 50 bee-hives]

5. TARGET SPECIES

Honey bees

6. INDICATION(S)

Treatment of varroosis (*Varroa destructor)*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Use instructions: Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Special precautions: Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

[not applicable]

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

Disposal: read package leaflet.

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

For animal treatment only.

[country specific prescription status]

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4146

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
PolyVar Yellow 275 mg bee-hive strip

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

Marketing authorisation holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PolyVar Yellow 275 mg bee-hive strip

Flumethrin

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

Yellow, plastic strips with 15 holes
Active substance: One bee-hive strip contains 275 mg flumethrin

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None.

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

7. TARGET SPECIES

Honey bee

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

In-hive use. Use at the bee-hive entrance as a gate.
Use two strips per standard bee-hive.

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 warning(s)”.

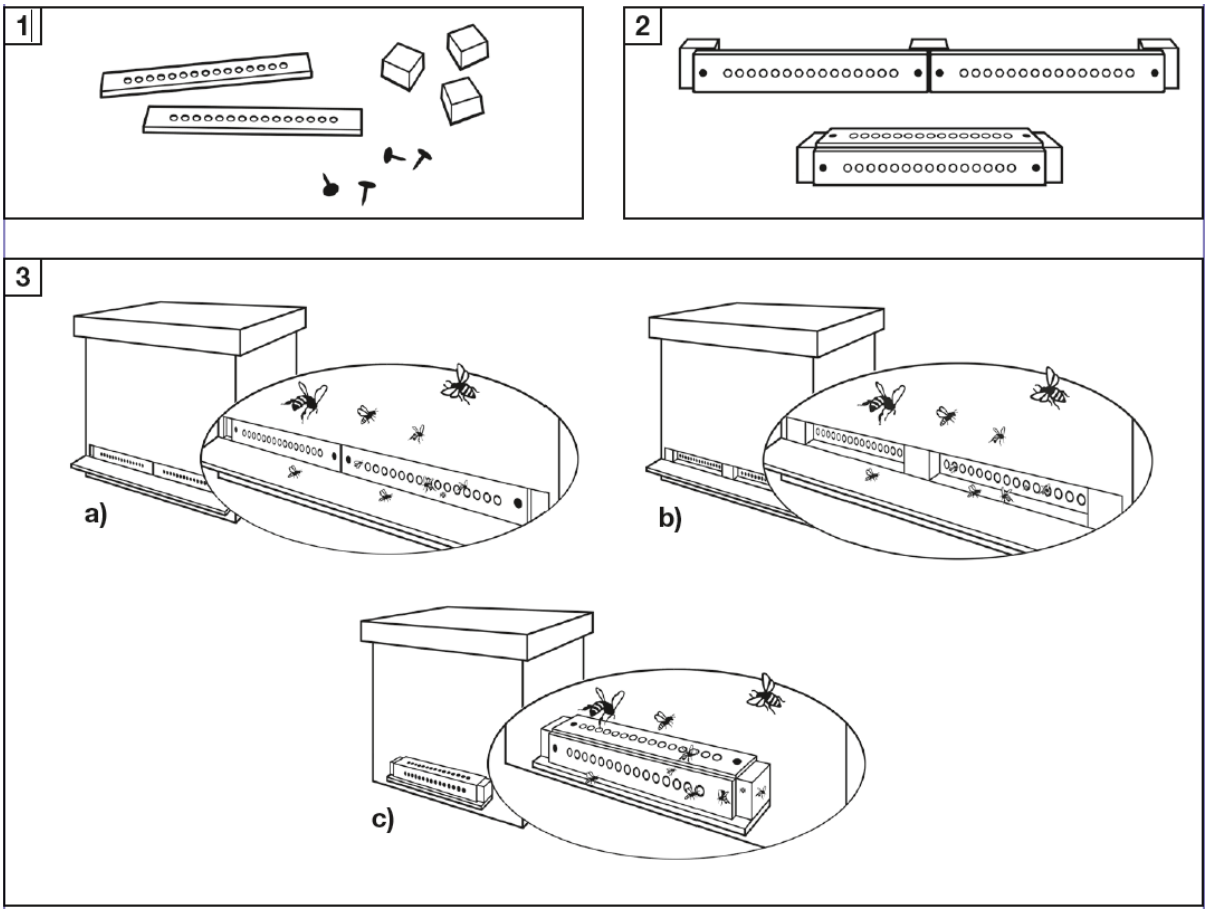
The bee-hive strip should be fitted at the entrance in a way that the bees are forced to enter or leave the hive only through the holes of the strip. The entire surface and the holes of the bee-hive strip should not be covered to ensure the contact of the bees with the strip and to ensure ventilation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



10. WITHDRAWAL PERIOD

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 after the expiry date stated on the label and carton.
Shelf life after first opening the immediate packaging: use immediately. Any remaining product should be discarded.

12. SPECIAL WARNING(S)

Special warnings for each target species:

All colonies located on the same apiary should be treated simultaneously.
The product should be used as part of an integrated varroa control programme.
As an effective method to reduce the risk of resistance selection PolyVar Yellow – 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 product could result in an increased risk of resistance development and could ultimately result in ineffective therapy and colony losses.
In general, it is recommended to test acaricide susceptibility at a regionallevel. This can be done by means of e.g., bioassays (testing whether live mites die when exposed to the active substance) or molecular analysis using PCR (sampling of dead mites to test for existence of resistance genes). In the case of existing resistance to pyrethroids PolyVar Yellow 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.

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.

Do not re-use bee-hive strip.

Special precautions for use in animals

After installation of the 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.
Polyvar Yellow has not been tested during periods of extremely hot weather. The 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.
Wash hands with cold water after fitting the bee-hive strips.

Interaction with other medicinal products and other forms of interaction:
None known.
Do not use simultaneously with other acaricides against varroosis.

Overdose (symptoms, emergency procedures, antidotes):
Due to the nature of the bee-hive strips overdosage is unlikely and signs of overdosage are not to be expected.

Incompatibilities:
None known.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

PolyVar Yellow (strips or empty sachets) should not enter water courses as this may be dangerous for fish and other aquatic organisms.

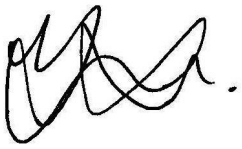
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Polyester/aluminium/ low density polyethylene foil bag Pack size:
Box containing 1 foil bag (10 bee-hive strips)
Box containing 10 foil bags (100 bee-hive strips)
Not all pack sizes may be marketed.

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.



Approved: 17 September 2020