# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

#### **CARTONS**

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayvarol 3.6 mg Bee-Hive Strips for Honey Bees.

#### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One Bee-hive strip contains:

Active substance
Flumethrin (85%) 4.23 mg
(equivalent to 3.6 mg Flumethrin 100%)

#### 3. PHARMACEUTICAL FORM

Bee-hive strips.

#### 4. PACKAGE SIZE

Carton contains 5 bags, each foil bag contains 4 bee-hive strips. Each strip contains 3.6 mg flumethrin.

Carton contains 200 bags, each foil bag contains 4 bee-hive strips. Each strip contains 3.6 mg flumethrin.

### 5. TARGET SPECIES

Honeybees.

# 6. INDICATION(S)

For the diagnosis and control of flumethrin sensitive *Varroa jacobsoni* in honeybees.

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Bayvarol strips are intended for in-hive use.

Bayvarol Strips are suspended into the spaces between the combs in the central brood

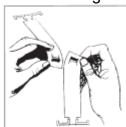
rearing area in such a way that they can be occupied by bees on both sides. Both tabs are bent outwards in the same direction at the marked fold lines and hooked over the top edge of the wooden frame (see Fig. 1).

For large colonies occupying several brood chambers, two strips can be joined together end-to-end which enables their insertion into and removal from the bee spaces without having to separate the brood chambers (see Fig. 2).

Fig. 1



Fig. 2



Normally developed colonies receive four strips.

Nuclei and young colonies and newly collected swarms receive half that dose i.e., two strips.

Large colonies occupying several brood chambers receive four strips per chamber, which are distributed over the central bee space in each brood chamber.

#### When to Use:

Best efficacy is to be expected when Bayvarol is used in late summer after the honey harvest. Ideally the strips should not be used during peak honey flow periods. However,

Bayvarol can be used at any time of the year for diagnosis or in severe infestations where there is a threat to the survival of the colony.

#### 1. Diagnosis

The strips are inserted into the colony for 24 hours.

Before inserting the strips the floor tray is covered with a clean sheet of paper. This is then checked for the presence of dead Varroa mites 24 hours later.

#### 2. Treatment

The strips should be left in the colonies for a maximum of six weeks and then removed.

#### 8. WITHDRAWAL PERIOD

No withdrawal period for honey is required regardless of when in the year Bayvarol is used.

Other bee produce should not be taken for human consumption until the spring following

treatment.

### 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

When using do not eat, drink or smoke. Wash hands after handling the strips, before meals and after work.

Avoid the strips coming into contact with honey to be harvested for human consumption.

#### 10. EXPIRY DATE

Exp: mm/yyyy

Do not open the foil bags until immediately prior to use. Once opened the strips should be used and **discarded within 6 weeks**. Do not use after the expiry date.

Discard date:

#### 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store away from food, drink and animal feedingstuffs.

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

Bayvarol should not enter water courses as this may be dangerous for fish and other aquatic organism. Therefore do not contaminate ponds, waterways and ditches with the strip or used packaging.

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

# 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

# 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

**UK Only** 

Elanco Europe Ltd. Form 2, Bartley Way

Bartley Wood Business

Park

Hook RG27 9XA

**United Kingdom** 

IE Only Bayer Ltd,

Animal Health Division,

The Atrium,

Blackthorn Road,

Dublin 18,

Ireland

Tel: 01 -2999313

ES Only

Bayer Hispania, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despí

(Barcelona)

# 16. MARKETING AUTHORISATION NUMBERS

<u>UK Only</u> <u>IE Only</u> <u>ES Only</u> Vm 00879/4125 VPA 10021/50/1 1713 ESP

AVM-GSL LM

# 17. MANUFACTURER'S BATCH NUMBER

**BN: XXXX** 

#### MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

**NATURE/TYPE: BLISTER STRIP** 

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayvarol 3.6 mg Bee-Hive Strips for Honey Bees. 3.6 mg Flumethrin

### 2. NAME OF THE MARKETING AUTHORISATION HOLDER

UK Only IE Only ES Only

Elanco Europe Ltd. Bayer Ltd, Bayer Hispania, S.L. Form 2, Bartley Way Animal Health Division, Bartley Wood Business The Atrium 08970 Sant Joan Despí

Bartley Wood Business The Atrium, 08970 Sant Park Blackthorn Road. (Barcelona)

Park Blackthorn Road,
Hook Dublin 18,
RG27 9XA Ireland

**United Kingdom** 

#### 3. EXPIRY DATE

Exp: mm/yyyy

### 4. BATCH NUMBER

**BN: XXXX** 

#### 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# 6. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children.

# 7. MARKETING AUTHORISATION NUMBER

<u>UK Only</u> <u>IE Only</u> <u>ES Only</u> Vm 00879/4125 VPA 10021/50/1 1713 ESP

AVM-GSL LM

#### 8. USE INSTRUCTIONS

For full information read package leaflet or carton before use.

Contains 4 strips.

Do not store above 25°C.

Do not open the foil bags until immediately prior to use.

# 8. WARNINGS

Bayvarol should not enter water courses as this may be dangerous for fish and other aquatic organism. Therefore do not contaminate ponds, waterways and ditches with the strip or used packaging.

# 9. MANUFACTURER

Manufactured by: KVP Pharma und Veterinär-Produkte GmbH, D-24106 Kiel, Germany

#### **PACKAGE LEAFLET**

Bayvarol 3.6 mg Bee-Hive Strips 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**

<u>UK Only</u> <u>IE Only</u> <u>ES Only</u>

Elanco Europe Ltd. Bayer Ltd, Bayer Hispania, S.L. Form 2, Bartley Way Animal Health Division, Bartley Wood Business The Atrium, Bayer Hispania, S.L. Av. Baix Llobregat, 3-5 08970 Sant Joan Despí

Park Blackthorn Road, (Barcelona)

Hook Dublin 18, RG27 9XA Ireland

United Kingdom

### <u>Manufacturer</u>

KVP Pharma und Veterinär-Produkte GmbH, Projensdorfer Str.324, D-24106 Kiel, Germany

# 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayvarol 3.6 mg Bee-Hive Strips for Honey Bees. Flumethrin

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

One Bee-hive strip contains:

Active substance

Flumethrin (85%) 4.23 mg

(equivalent to 3.6 mg Flumethrin 100%)

Low density polyethylene

#### 4. INDICATION(S)

For the diagnosis and control of flumethrin sensitive *Varroa jacobsoni* in honeybees.

#### 5. CONTRAINDICATIONS

None

#### 6. ADVERSE REACTIONS

There were no adverse effects in those colonies treated with Bayvarol strips and those with a placebo control.

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

#### 7. TARGET SPECIES

Honeybees.

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

Normally developed colonies receive four strips.

Nuclei and young colonies and newly collected swarms receive half that dose i.e., two strips.

Large colonies occupying several brood chambers receive four strips per chamber, which are distributed over the central bee space in each brood chamber.

#### 9. ADVICE ON CORRECT ADMINISTRATION

Bayvarol strips are intended for in-hive use.

Bayvarol Strips are suspended into the spaces between the combs in the central brood rearing area in such a way that they can be occupied by bees on both sides. Both tabs are bent outwards in the same direction at the marked fold lines and hooked over the top edge of the wooden frame (see Fig. 1).



For large colonies occupying several brood chambers, two strips can be joined together end-to-end which enables their insertion into and removal from the bee spaces without having to separate the brood chambers (see Fig. 2).



#### When to Use:

Best efficacy is to be expected when Bayvarol is used in late summer after the honey harvest. Ideally the strips should not be used during peak honey flow periods. However, Bayvarol can be used at any time of the year for diagnosis or in severe infestations where there is a threat to the survival of the colony.

### 1. Diagnosis

The strips are inserted into the colony for 24 hours.

Before inserting the strips the floor tray is covered with a clean sheet of paper. This is then checked for the presence of dead Varroa mites 24 hours later.

#### 2. Treatment

The strips should be left in the colonies for a **maximum of six weeks and then removed**.

#### 10. WITHDRAWAL PERIOD

No withdrawal period for honey is required regardless of when in the year Bayvarol is used.

Other bee produce should not be taken for human consumption until the spring following treatment.

#### 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

Store away from food, drink and animal feedingstuffs.

Do not use after the expiry date stated on the carton.

Do not open the foil bags until immediately prior to use. Once opened the strips should be used and **discarded within 6 weeks**. Do not use after the expiry date.

# 12. SPECIAL WARNING(S)

Wash hands after handling the strips, before meals and after work. When using do not eat drink or smoke.

Do not open foil bags until immediately prior to use.

Avoid the strips coming into contact with honey to be harvested for human consumption.

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

Bayvarol should not enter water courses as this may be dangerous for fish and other aquatic organism. Therefore do not contaminate ponds, waterways and ditches with the strip or used packaging.

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

#### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

#### 15. OTHER INFORMATION

4 bee-hive strips per bag 5 bags per carton and 200 bags per carton. Not all pack sizes may be marketed.

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Approved 14 October 2020