

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayvarol 3.6 mg Bee-hive strips for Honey Bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One Bee-hive strip contains:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee-hive strips
Milky white plastic strips.

4. CLINICAL PARTICULARS

4.1 Target species

Honeybees

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 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. Such programme includes, among other measures, rotation of products and systematic monitoring of mite burden during the year.

As an effective method to reduce the risk of resistance selection, rotation with products containing active substances from other chemical classes should be applied. As flumethrin and tau-fluvalinate belong to the same class (“pyrethroids”) they are not suitable for rotation with each other.

Inappropriate use of the product may increase the risk of resistance development and ultimately result in ineffective therapy and colony losses.

Bee colonies should be monitored routinely to check the level of mite infestation (*Varroa*) (e.g., with established standard tests like continuous monitoring of natural mite fall using a sticky insert tray or assessing mite load per 100 bees).

In the case of existing resistance to pyrethroids, Bayvarol Strips should not be applied. Where resistance to pyrethroids has been seen in the past, retesting of the current status of the colony may be considered, as reversion to susceptibility can occur over several years.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

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.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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 upwards in the same direction at the marked fold lines and hooked over the top edge of the wooden frame.

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 beespaces without having to separate the brood chambers.

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 beespaces in each brood chamber.

Time and Duration of 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 the 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.

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.

Treatment

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

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

Studies in which double the normal number of strips were used during the winter period showed no adverse effects on the bees or any adverse effect on subsequent breeding.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides
ATC vet code: QP53AC05

5.1 Pharmacodynamic properties

Flumethrin is a synthetic pyrethroid compound acting by pre- and post-synaptic induction of repetitive action potentials and perturbation of axonal impulses by changes in K⁺ / Na⁺ permeability.

Flumethrin is a type II synthetic pyrethroid and causes a long-lasting prolongation of the normally transient increase in sodium permeability of the nerve membrane during excitation, resulting in longlasting trains of repetitive firing. The α -cyano group on the phenoxy-fluorobenzyl alcohol moiety is considered to be responsible for the long-lasting prolongation of sodium permeability. The type II pyrethroids produce a distinct poisoning syndrome which is characterised by choreoathetosis (sinuous writhing of the whole body) and salivation.

5.2 Pharmacokinetic particulars

ABSORPTION: Percutaneous absorption in mammals is minimal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Low density polyethylene

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

Shelf-life after first opening the immediate packaging: 6 weeks

6.4. Special precautions for storage

Do not store above 25°C.

Store away from food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

Aluminium/Polyester/PE foil bag containing 4 bee-hive strips

Pack size(s):

5 bags per carton and 200 bags per carton.

Not all pack sizes may be marketed.

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

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.

7. MARKETING AUTHORISATION HOLDER

Elanco Animal Health GmbH
Alfred-Nobel-Str. 50
40789 Monheim
Germany

8. MARKETING AUTHORISATION NUMBER(S)

[to be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[to be completed in accordance with national requirements after conclusion of the MR phase]

10. DATE OF REVISION OF THE TEXT

01/2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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.

Flumethrin

2. STATEMENT OF ACTIVE 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 destructor* 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(S)

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

Expiry/EXP {month/year}

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 feeding stuffs.

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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Animal Health GmbH
Alfred-Nobel-Str. 50
40789 Monheim
Germany

16. MARKETING AUTHORISATION NUMBER(S)

[to be completed nationally]

17. MANUFACTURER’S BATCH NUMBER

Batch No./Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

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

Elanco Animal Health GmbH
Alfred-Nobel-Str. 50
40789 Monheim
Germany

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

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 sight and reach of children.

7. MARKETING AUTHORISATION NUMBER

[to be completed nationally]

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 + Veterinär Produkte GmbH, D-24106 Kiel, Germany

B. PACKAGE LEAFLET

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:

Elanco Animal Health GmbH
Alfred-Nobel-Str. 50
40789 Monheim
Germany

Manufacturer responsible for batch release:

KVP Pharma + 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 destructor* 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, 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.

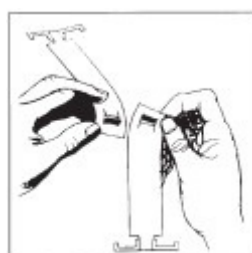
9. ADVICE ON CORRECT ADMINISTRATION

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(S)

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 sight and reach of children.

Do not store above 25°C.

Store away from food, drink and animal feeding stuffs.

Do not use this veterinary medicinal product after the expiry date which is 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. The expiry date refers to the last day of that month.

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. Such programme includes, among other measures, rotation of products and systematic monitoring of mite burden during the year.

As an effective method to reduce the risk of resistance selection, rotation with products containing active substances from other chemical classes should be applied. As flumethrin and tau-fluvalinate belong to the same class (“pyrethroids”) they are not suitable for rotation with each other.

Inappropriate use of the product may increase the risk of resistance development and ultimately result in ineffective therapy and colony losses.

Bee colonies should be monitored routinely to check the level of mite infestation (Varroa) (e.g., with established standard tests like continuous monitoring of natural mite fall using a sticky insert tray or assessing mite load per 100 bees).

In the case of existing resistance to pyrethroids, Bayvarol Strips should not be applied. Where resistance to pyrethroids has been seen in the past, retesting of the current status of the colony may be considered, as reversion to susceptibility can occur over several years.

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

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.

Overdose (symptoms, emergency procedures, antidotes):

Studies in which double the normal number of strips were used during the winter period showed no adverse effects on the bees or any adverse effect on subsequent breeding.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

01/2024

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.