

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

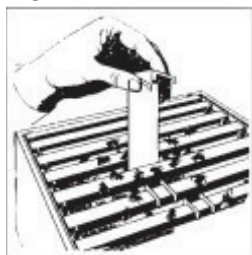


Fig. 2



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