

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Optivar 500 mg bee-hive strips for honey bees

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each strip contains:

### Active substance:

Amitraz 500 mg

### Excipients:

| Qualitative composition of excipients and other constituents |
|--|
| Ethylene Vinyl Acetate copolymer                             |
| Calcium oxide (E529)   |
| Erucamide  |

Rectangular opaque and white to beige bee-hive strips.

Strips are paired together with a pre-cut line and feature holes and a built-in hanging system for easy suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Honey bee (*Apis mellifera*)

### 3.2 Indications for use for each target species

Treatment of varroosis due to *Varroa destructor* sensitive to amitraz.

### 3.3 Contraindications

None.

### 3.4 Special warnings

All colonies in the same apiary should be treated simultaneously to avoid re-infestation.

Do not re-use the strips.

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

Bee colonies should be monitored routinely for the level of varroa mite infestation specifically before the treatment and for a period thereafter.

Product efficacy is not directly affected by external temperature but may be influenced by the activity of the bees. See section 3.9 Administration routes and dosage.

The veterinary medicinal product should be used as part of an integrated varroa control program and treatment rotation using veterinary medicinal products containing different active substances of different chemical classes should be applied.

Amitraz resistance has been reported in some populations of varroa mites.

In regions with suspected amitraz resistance, it is recommended that the use of the veterinary medicinal product should be based on results of susceptibility testing, and it is recommended to seek advice from your veterinarian or local bee inspector.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Do not exceed or reduce the recommended dose and recommended duration of use.

Remove the strips at the end of treatment.

The safety profile for the product has not been established in weak colonies, i.e. those colonies containing a number of bees that is lower than expected for the time of year.

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

This veterinary medicinal product contains amitraz which can lead to neurological side-effects in humans.

Amitraz is a monoamine oxidase inhibitor. Therefore, take particular care if you are taking monoamine oxidase inhibitors, hypotensive treatment or if you have diabetes.

Personal protective equipment consisting of impervious gloves and the usual beekeeping protective clothing should be worn when handling the veterinary medicinal product.

Avoid contact with skin. In case of contact, wash thoroughly with soap and water.

Avoid contact with eyes. In case of contact, rinse with plenty of water immediately.

If irritation occurs, seek immediate medical advice and show the package leaflet or label to the physician

Do not eat, drink or smoke during the use of the veterinary medicinal product.

Wash your hands thoroughly after use.

Keep children away during application.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

#### Special precautions for the protection of the environment:

Avoid entry to water courses including residual and waste water as amitraz could be dangerous for fish and aquatic organisms.

### 3.6 Adverse events

Honey bees:

|  |                       |
|--|-----------------------|
| Very rare<br>( $<1$ animal/10,000 animals treated<br>including isolated reports) | Behavioural disorder* |
|--|-----------------------|

\*A transient change in behaviour (e.g., fleeing reaction, aggressive behaviour) may be observed when the strips are first placed in the hive. This is believed to be a defensive behaviour rather than an adverse reaction to the veterinary medicinal product, per se.

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

The toxicity of amitraz is increased in the presence of copper salts and the therapeutic activity is reduced in the presence of piperonyl butoxide. The concomitant use of these substances with amitraz should be avoided.

Amitraz has an antagonistic interaction with oxalic acid due to hydrolytic breakdown of amitraz under acidic conditions, and amitraz pretreatment increased the toxicity of tau-fluvalinate 5-fold.

Do not use any other parasiticide product at the same time.

### 3.9 Administration routes and dosage

In-hive use.

Each strip contains 500 mg of amitraz.

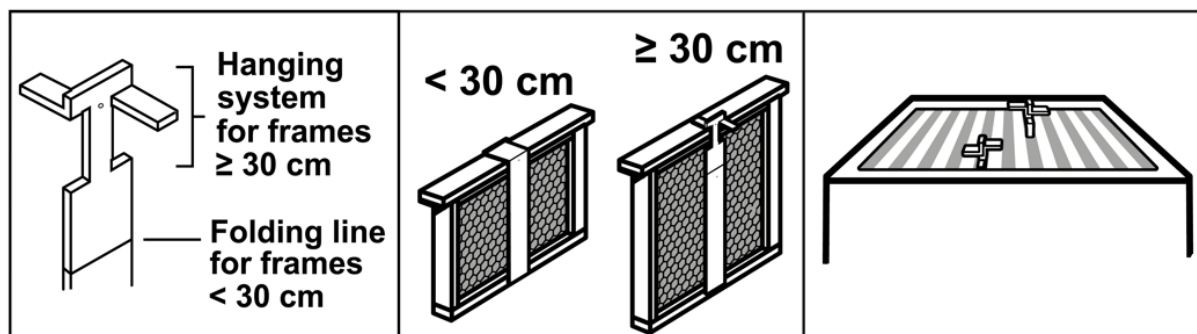
Use two strips per brood chamber.

- For a hive with a single brood chamber: use 2 strips corresponding to 1 g of amitraz.
- For a hive with a double brood chamber: use 4 strips corresponding to 2 g of amitraz.

Strips are suitable for different sizes of frames due to their adaptable length. Do not cut the strip.

Separate the double strips: gently tear from top to bottom to avoid damaging the hanging system. Suspend the strips using the hanging system, adapting it to the frame height (see pictures).

- For frames  $\geq 30$  cm: Bend the flaps of the hanging system in opposite directions to suspend the strips on the frames.
- For frames  $< 30$  cm: Bend the strip above the frame along the folding line.



Hang each strip between two comb frames inside the brood area or the bee cluster ensuring a minimum distance of 2 frames between strips.

Place the strips so that bees have free access to both sides.

The strips can also be suspended using one of the two holes (chosen according to the frame height), with the help of a small nail, a toothpick, or a hook.

#### 10-week treatment duration

The standard treatment duration is 10 weeks.

This duration is recommended for:

- Colonies with moderate to high brood levels at the start of treatment,
- Colonies with sustained brood presence during treatment,
- Colonies using two brood boxes,
- Situations where brood development cannot be reliably assessed.

### 6-week treatment duration

A treatment duration of 6 weeks may be considered only when the following conditions are met:

- Brood levels are low at the start of treatment (approximately one brood frame, i.e.  $\leq 10000$  brood cells),

and

- No brood is present in the colony at 5-6 weeks after treatment initiation.

If either of these conditions is not fulfilled, the strips must remain in place for the full 10-week treatment duration.

The decision to apply a 6-week treatment duration is based on an assessment of colony development and brood dynamics.

In case the strips are covered by propolis and/or wax, at mid-treatment, it is possible to gently scrape the strips using a hive tool. Afterwards, the strips should be placed back into the hive and repositioned, if necessary, to follow the application instructions above (in case of changes in the bee cluster or brood area).

The product should be applied when bees are still active, i.e. before they form a winter cluster, the exact timing of which can vary between climatic zones.

The recommended time for treatment is when honey supers are not present after the last honey harvest (late summer/autumn) and before spring honey-flow period. Infestation monitoring is recommended to determine the best time for treatment.

Remove the strips before the honey flow starts.

The need for and frequency of re-treatment(s), as part of integrated pest management, should be based on professional advice, and should take into account the local epidemiological situation.

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

No adverse effects were observed when the product was administered at twice the recommended dose.

### **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.

Do not extract honey from the brood chamber.

Do not harvest honey for human consumption while the treatment is in place.

Brood combs should be replaced with new foundation at least every three years.

Do not reuse brood frames as honey frames.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP53AD01.

### **4.2 Pharmacodynamics**

Amitraz is a formamidine acaricide that acts as an agonist on octopamine receptors causing an over-stimulation of octopaminergic synapses in acari, resulting in tremors, convulsions, detachment and death of the parasite.

Resistance to amitraz in *Varroa destructor* is associated with mutations in the  $\beta$ -adrenergic-like octopamine receptor.

### **4.3 Pharmacokinetics**

Amitraz is delivered to the surface of the strips and acts by contact with bees.

The Ethylene Vinyl Acetate used in this veterinary medicinal product increases the speed and quantity of amitraz migration from the strip to its surface at the start of the treatment. This was shown in an *in-vitro* experimental test, comparing the release of amitraz over 96 hours between two different formulations of amitraz strips.

The pharmacokinetics of amitraz in bees is unknown.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Not applicable.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 1 month.

### **5.3 Special precautions for storage**

Store in the original package in order to protect from light.

Keep the package tightly closed

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

### **5.4 Nature and composition of immediate packaging**

Heat-sealed multi-layer sachet made of two films: PE/PA/Alu/PET and PE/Alu/oPA.

#### Pack sizes:

4 strips

10-strips

12 strips

60-strips

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 amitraz 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**

VETO-PHARMA

**7. MARKETING AUTHORISATION NUMBER(S)**

VPA22827/002/001

**8. DATE OF FIRST AUTHORISATION**

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).