

**SUMMARY OF PRODUCT CHARACTERISTICS**

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

**Amicel Varroa**

Solution for bee-hive strip

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One ml contains:

**Active substance:**

Amitraz.....25 mg

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Solution for bee-hive strip

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Honeybees (*Apis mellifera*).

**4.2 Indications for use, specifying the target species**

Treatment of external parasitosis caused by *Varroa destructor* sensitive to amitraz.

**4.3 Contraindications**

None known.

**4.4 Special warnings for each target species**

They should be treated simultaneously all apiary hives to prevent re-infestation pillage. Do not re-use the strips. An antiparasitic drug misuse can result in an increased risk of development of resistance, resulting in ineffective therapy.

The administration of the medicinal product should be done in periods with little breeding in the hive (when the number of breeding is low).

Doses higher than the recommended will not increase the efficacy of the medicinal product.

**4.5 Special precautions for use**

**Special precautions for use in animals**

Do not use more than the indicated amount (10 ml solution) to prepare each strip.

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

Amitraz is a monoamine oxidase inhibitor (MAOI), so people taking medication containing MAOIs should take special care.

Use personal protective equipment consisting of rubber gloves when handling the veterinary medicine and placing into the hive.

Do not eat, drink or smoke during use.

Wash hands thoroughly with water after handling the product.

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

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

#### **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**

In-hive use.

##### Treatment of the hive

500 mg of amitraz per hive. This dose is reached by placing two strips per hive; each strip containing 250 mg amitraz.

##### Strip preparation

Apply homogeneously 10 ml of the solution in the strip, between 6 and 12 hours before placing it into the hive. The solution should be applied on one side of the strip and let it spread and penetrate before placing it into the hive.

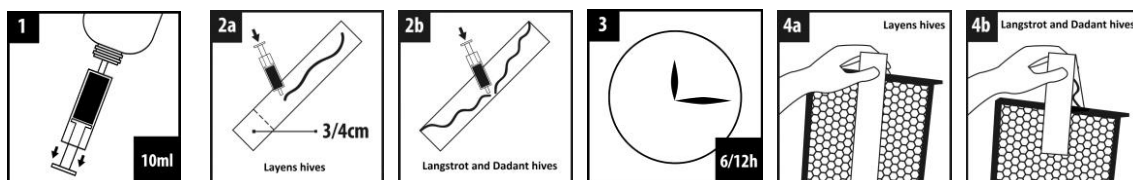
- Layens hives: spread the product evenly and left without impregnating 3-4 cm at the top of the strip to allow easy handling by the operator.
- Langstrot and Dadant hives (vertical design): impregnate the strip in two directions from vertices, from right to left, and from left to right, folding the strip in half to insert it in the hive.

##### Placing strips

The strips are placed in the hive box that corresponds to the center of the area of breeding; the placing site of the first and second stripe can match.

- Day 1: Place the first strip.
- Day 12: Place the second strip.
- Day 35: Remove both strips. If cellulose remains are observed at the bottom of the hive, also remove it.

The medicinal product should be administrated in periods with little breeding in the hive.



#### **4.10 Overdose (symptoms, emergency procedures, antidotes)**

The safety of this medicinal product was not assessed for doses higher than the recommended. It is recommended do not exceed the indicated dose.

#### **4.11 Withdrawal period**

Honey: Zero days.

Do not use during honey flow.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents

ATCvet code: QP53AD01

### **5.1 Pharmacodynamic properties**

Amitraz is a parasitocidal belonging to the group of formamidine insecticides.

The mechanism of action of amitraz type is neurotoxic. It acts primarily as octopaminérgicos inhibitory receptors in the central nervous system (CNS) of ectoparasites inducing an increased neuronal activity, abnormal behavior, detachment and death.

### **5.2 Pharmacokinetic particulars**

The bees contact with amitraz strip allows impregnation of Varroa's external cuticle and in consequence of such contact the antiparasite acts.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Bis (2,6-diisopropylphenyl)carbodiimide (Stabaxol<sup>®</sup>1)

Hydrocarbon, C9, aromatic (Solvesso<sup>®</sup> 100)

Refined corn oil

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 9 months.

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

Shelf-life after reconstitution according to directions: 35 days.

### **6.4 Special precautions for storage**

Store below 25 °C.

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

Bottle of high density polyethylene (HDPE) with a shutter of low density polyethylene (LDPE) and a plug of high density polyethylene (HDPE) with seal cap.

#### Pack sizes

Cardbox with one 250 ml bottle, 25 strips cellulose fibres and a 10 ml graduated syringe of polypropylene/polyethylene.

Cardbox with one 1 l bottle, 100 strips cellulose fibres and a 10 ml graduated syringe of polypropylene/polyethylene.

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**

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

Amicel Varroa should not enter water courses as this may be dangerous for fish and other aquatic organisms.

**7. MARKETING AUTHORISATION HOLDER**

Laboratorios Maymó, S.A.  
Via Augusta, 302  
08017 Barcelona (Spain)

**8. MARKETING AUTHORISATION NUMBER**

3157 ESP

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorization: 2 January 2015

**10. DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

**Supplying conditions:** To be supplied only on veterinary prescription.

**Administration conditions:** To be administer by a veterinary surgeon or under their direct responsibility.