

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Amicel Varroa**  
**Solution for bee-hive strips**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:  
Laboratorios Maymó, S.A.  
Vía Augusta, 302  
08017 Barcelona  
España

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

Amicel Varroa  
Solution for bee-hive strips  
Amitraz

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

Each ml contains:  
**Active substance:**  
Amitraz.....25 mg  
excipients, q.s

**4. INDICATION(S)**

Treatment of external parasitosis due to *Varroa destructor* sensitive to amitraz.

**5. CONTRAINDICATIONS**

None.

**6. ADVERSE REACTIONS**

None known.

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 (*Apis mellifera*).

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

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.
- Langstroth 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 frame that corresponds to the center of the breeding area; 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 administration of the medicinal product should be done in periods with little breeding in the hive

## **9. ADVICE ON CORRECT ADMINISTRATION**

## **10. WITHDRAWAL PERIOD(S)**

Honey: Zero days.

Do not use during honey flow.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store below 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or on the carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 6 months

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

## **12. SPECIAL WARNING(S)**

### Special warnings for each target species:

All the hives in the apiary should be treated simultaneously to prevent re-infestation due to robbery.

Misuse of antiparasitic drugs can result in an increased risk of development of resistance and could ultimately result in ineffective therapy.

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.

### 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 veterinary medicinal product to animals:

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

Personal protective equipment consisting of rubber gloves should be worn when preparing and placing the strips.

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.

### Pregnancy, lactation and lay:

Not applicable.

### Interaction with other medicinal products and other forms of interaction:

None known.

### 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.

### Incompatibilities:

None known

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

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

## **15. OTHER INFORMATION**

### Pack sizes:

A cardboard box with 1 bottle of 250 ml, 25 strips made of cellulose fibres and one graduated syringe of 10 ml polypropylene/polyethylene.

A cardboard box with 1 bottle of 1 litre, 100 strips made of cellulose fibres and one graduated syringe 10 ml of polypropylene/polyethylene.

Not all pack sizes may be marketed.

### **MARKETING AUTHORISATION NUMBER**