

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amicel Varroa
Solution for bee-hive strips

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Amitraz.....25 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for bee-hive strips

4. CLINICAL PARTICULARS

4.1 Target species

Honeybees (*Apis mellifera*).

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 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. 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 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.

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.
- 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

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 parasiticide belonging to the group of formamidine insecticides.

The mechanism of action of amitraz is neurotoxic. It acts primarily as an inhibitor of octopaminergic 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 ®1)

Heptane

Refined maize oil

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf-life after first opening the immediate packaging: 6 months.

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

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

Pack sizes:

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

A cardboard box with 1 bottle of 1 litre, 100 strips made of cellulose fibres and 1 graduated syringe of 10 ml 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.U.
Via Augusta, 302
08017 Barcelona (Spain)

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

Date of first authorization: 2 January 2015

10. DATE OF REVISION OF THE TEXT

May 2024

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.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 220 ml, 250 ml and 1000 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amicel Varroa
Solution for bee-hive strips
Amitraz

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for bee-hive strips

4. PACKAGE SIZE

220 ml
250 ml
1 litre

5. TARGET SPECIES

Honeybees (*Apis mellifera*).

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Honey: Zero days.
Do not use during honey flow

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by 6 months

Once reconstituted, use by 35 days.

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Laboratorios Maymó, S.A.U.

Via Augusta, 302

08017 Barcelona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/000/000

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE

Label bottles 220 ml, 250 ml and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amicel Varroa
Solution for bee-hive strips
Amitraz

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for bee-hive strips

4. PACKAGE SIZE

220 ml
250 ml
1 litre

5. TARGET SPECIES

Honeybees (*Apis mellifera*).

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Honey: Zero days.
Do not use during honey flow

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}>

Once opened, use by 6 months

Once reconstituted, use by 35 days.

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

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

Laboratorios Maymó, S.A.U.

Via Augusta, 302

08017 Barcelona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

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.U.
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

January 2025

15. OTHER INFORMATION

Pack sizes:

A cardboard box with 1 bottle of 220 ml, 22 strips made of cellulose fibres and 1 graduated syringe of 10 ml of polypropylene/polyethylene.

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