

[Version 8.1,01/2017]

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 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

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.
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 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

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.

Via Augusta, 302

08017 Barcelona (Spain)

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

Lot {number}