

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{SACHET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apivar 500 mg bee-hive strips for honey bees

2. STATEMENT OF ACTIVE SUBSTANCES

Each strip contains:
Amitraz 500 mg

3. PHARMACEUTICAL FORM

Bee-hive strips.

4. PACKAGE SIZE

10 strips
60 strips

5. TARGET SPECIES

Honey bees

6. INDICATION(S)

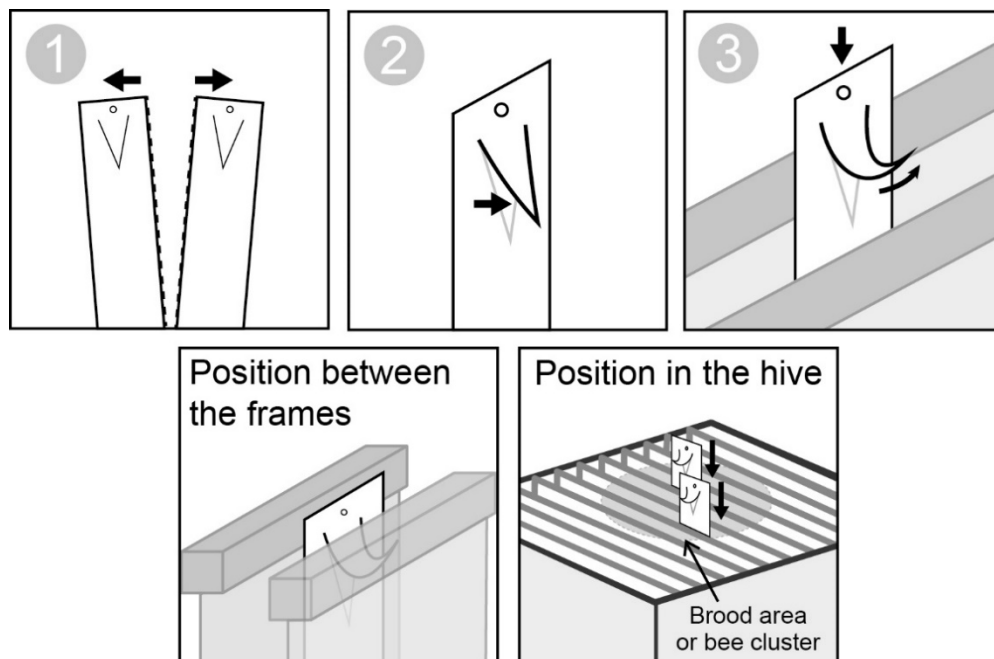
For OTC products: Treatment of varroosis due to *Varroa destructor* sensitive to amitraz in honey bees.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In-hive treatment:
Use two strips per hive (i.e. 1g of amitraz per hive).

1. Separate the double strip.
2. Push the strip's V-shaped die-cut outside.
3. Push each strip between the head of two frames **inside the brood area or the bee cluster** with a minimum distance of 2 frames between strips. The strips should be placed in such a way that the bees can have free access to both sides.

Alternatively, the strips can be hung by the hole in the V-shaped die-cut, using a small clove (or toothpick or hanger) fixed on the frame.



If brood is not present or at its lowest level, the strips can be removed after 6 weeks of treatment. If brood is present, leave the strips in place for 10 weeks and remove the strips at the end of treatment. In case the strips are covered by propolis and/or wax, at mid-treatment, it is possible to gently scratch the strips using a hive tool. Then, the strips should be placed in the hive again and repositioned, if necessary, in order to match the application instructions above (in case of changes in the bee cluster or brood area).

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

8. WITHDRAWAL PERIOD(S)

Honey: zero days.

Do not use during honey flow.

Do not extract honey from the brood chamber.

Do not harvest honey when the treatment is in place.

Brood combs should be replaced with new foundation at least every three years. Do not recycle brood frames as honey frames.

9. SPECIAL WARNING(S), IF NECESSARY

Special warnings for each target species:

It is recommended not to use the product during the honey flow but after the honey harvest. See section “Amount to be administered and administration route”.

Do not cut the strips.

All colonies in the same apiary should be treated simultaneously to avoid reinfestation.

Do not re-use the strips.

The safety and efficacy of the product has only been investigated in hives with a single brood chamber (dose of 2 strips per hive/brood chamber). Use in hives with more than one brood chamber is not recommended.

Inappropriate use of the 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.

The product should be used as part of an integrated varroa control program and treatment rotation should be applied.

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

In case of use in regions with suspected amitraz resistance, it is recommended that the use of the product should be based on results of susceptibility testing (e.g.

Beltsville test), and it is recommended to seek advice from your veterinarian or local bee inspector.

Special precautions for use in animals

Do not exceed or reduce the recommended dose and recommended duration of use. Remove the strips at the end of treatment.

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

This 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. Amitraz may cause skin sensitization (allergic reactions, particularly skin rashes).

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.

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

If irritation occurs, seek medical advice immediately and show the package leaflet of the label to the physician.

Do not eat, drink or smoke whilst handling the product.

Keep children away during application of the product.

Wash hands after use.

Do not inhale or ingest.

Other precautions

Do not throw strips or empty sachets in ponds or streams, as the product could be dangerous for fish and aquatic organisms.

10. EXPIRY DATE

EXP MM/YYYY

Once opened use immediately.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

Store in the original closed package. Protect from light.

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

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

The veterinary medicinal product should not enter watercourses as this may be dangerous for fish and aquatic organisms.

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

For animal treatment only.

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

VETO PHARMA SAS
12-14 rue de la Croix Martre
91120 Palaiseau
FRANCE
Tel.: +33 1 69 18 84 80
Fax: +33 1 69 28 12 93
Email: info@vetopharma.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 51567/3000

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
APIVAR 500 mg Amitraz Bee-hive strips for honey bees.

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

Marketing authorisation holder:

VETO PHARMA SAS
12-14 rue de la Croix Martre
91120 Palaiseau
FRANCE

Manufacturer responsible for batch release:

VETO PHARMA SAS
Zone artisanale de Champrue
36310 Chaillac
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apivar 500 mg bee-hive strips for honey bees

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

Each 15g strip contains:

Amitraz (active substance).....500 mg

Ethylene vinyl acetate.....qs 15g

Rectangular translucent homogeneous rigid strip with a V-shape cutting at one end
and a hole above.

4. INDICATION(S)

Treatment of varroosis due to *Varroa destructor* sensitive to amitraz in honey bees.

5. CONTRAINDICATIONS

Do not use in case of known resistance to amitraz.

6. ADVERSE REACTIONS

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 product, per se.

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. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Honey bees.

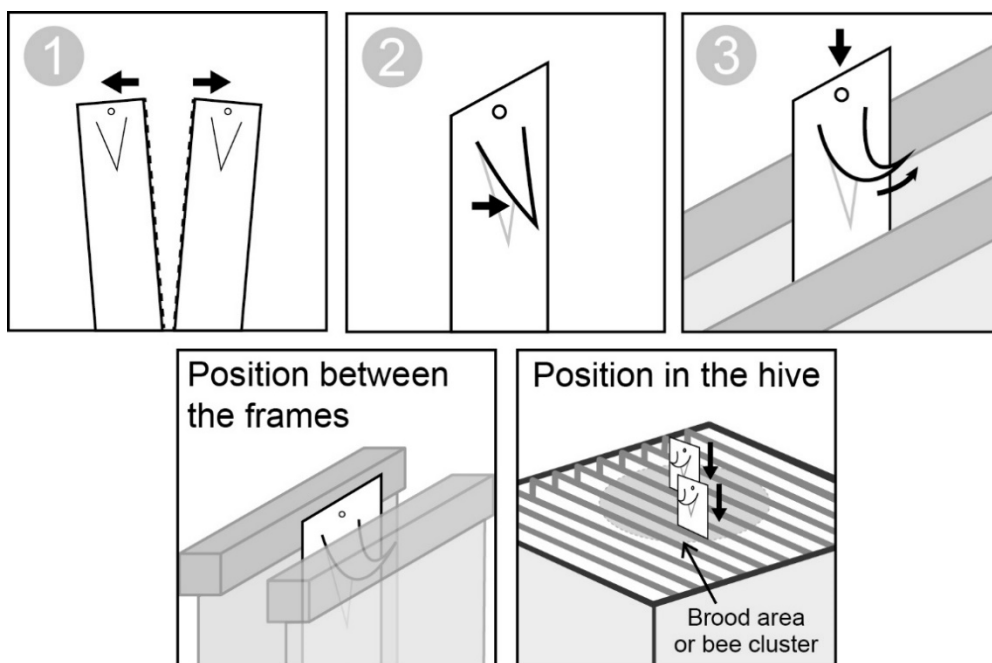
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In-hive treatment:

Use two strips per hive (i.e. 1g of amitraz per hive).

1. Separate the double strip.
2. Push the strip's V-shaped die-cut outside.
3. Push each strip between the head of two frames **inside the brood area or the bee cluster** with a minimum distance of 2 frames between strips. The strips should be placed in such a way that the bees can have free access to both sides.

Alternatively, the strips can be hung by the hole in the V-shaped die-cut, using a small clove (or toothpick or hanger) fixed on the frame.



If brood is not present or at its lowest level, the strips can be removed after 6 weeks of treatment. If brood is present, leave the strips in place for 10 weeks and remove the strips at the end of treatment. In case the strips are covered by propolis and/or wax, at mid-treatment, it is possible to gently scratch the strips using a hive tool. Then, the strips should be placed in the hive again and repositioned, if necessary, in order to match the application instructions above (in case of changes in the bee cluster or brood area).

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

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Honey: zero days.

Do not use during honey flow.

Do not extract honey from the brood chamber.

Do not harvest honey when the treatment is in place.

Brood combs should be replaced with new foundation at least every three years. Do not recycle brood frames as honey frames.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Store in the original closed package. Protect from light.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the pack.

The expiry date refers to the last day of that month.

Use immediately after first opening and discard any unused product.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:

It is recommended not to use the product during the honey flow but after the honey harvest. See section "Amount to be administered and administration route".

Do not cut the strips.

All colonies in the same apiary should be treated simultaneously to avoid reinfestation.

Do not re-use the strips.

The safety and efficacy of the product has only been investigated in hives with a single brood chamber (dose of 2 strips per hive/brood chamber). Use in hives with more than one brood chamber is not recommended.

Inappropriate use of the 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.

The product should be used as part of an integrated varroa control program and treatment rotation should be applied.

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

In case of use in regions with suspected amitraz resistance, it is recommended that the use of the product should be based on results of susceptibility testing (e.g. Beltsville test), and it is recommended to seek advice from your veterinarian or local bee inspector.

Special precautions for use in animals

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

Remove the strips at the end of treatment.

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

This 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. Amitraz may cause skin sensitization (allergic reactions, particularly skin rashes). 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. Personal protective equipment consisting of impervious gloves and the usual beekeeping protective clothing should be worn when handling the product. If irritation occurs, seek medical advice immediately and show the package leaflet of the label to the physician. Do not eat, drink or smoke whilst handling the product. Keep children away during application of the product. Wash hands after use. Do not inhale or ingest.

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

Overdose (symptoms, emergency procedures, antidotes):

At five times the recommended dosage applied for 6 weeks, the colonies clustered on very hot days. No other sign was observed. At 1.5 times the recommended dosage applied for 10 weeks, no apparent side effects were observed in bees.

Incompatibilities:

None known.

Other precautions

Do not throw strips or empty sachets in ponds or streams, as the product could be dangerous for fish and aquatic organisms.

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

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

The veterinary medicinal product should not enter watercourses as this may be dangerous for fish and aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

Pack sizes:

10 strips

60 strips

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line and a small flourish.

Approved 14 July 2022