

*[Version 9,  
03/2022] corr. 11/2022*

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apivar 500 mg amitraz bee-hive strips for honey bees (AT, BE, BG, CY, CZ, DE, EL, FR, HU, LT, RO, SK)  
Apivar 500 mg bee-hive strips for honey bees (HR, IE, PL, SI, UK(NI))  
Apivar vet 500 mg bee-hive strips (SE, NO, FI)  
Apivar (DK)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 g strip contains:

**Active substance :** Amitraz 500 mg

**Excipient :**

<b>Qualitative composition of excipients and other constituents</b>
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Ethylene vinyl acetate
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Rectangular translucent homogeneous rigid strip with a V-shape cutting at one end and a hole above.  
“Apivar” inscription on the edge of each strip.  
Strips are attached by two with a pre-cut line.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Honey bees – *Apis mellifera*.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

Do not use in case of known resistance to amitraz.

### 3.4 Special warnings

It is recommended not to use the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product should be based on results of susceptibility testing, and it is recommended to seek advice from your veterinarian or local bee inspector.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary medicinal product.

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

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

Keep children away during application of the veterinary medicinal product.

Wash hands after use.

Do not inhale or ingest.

#### Special precautions for the protection of the environment:

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

### 3.6 Adverse events

Honey bees

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorder <sup>1</sup>
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<sup>1</sup>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 veterinary medicinal product, per se.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system.

See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Not applicable.

### 3.8 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 veterinary medicinal product at the same time.

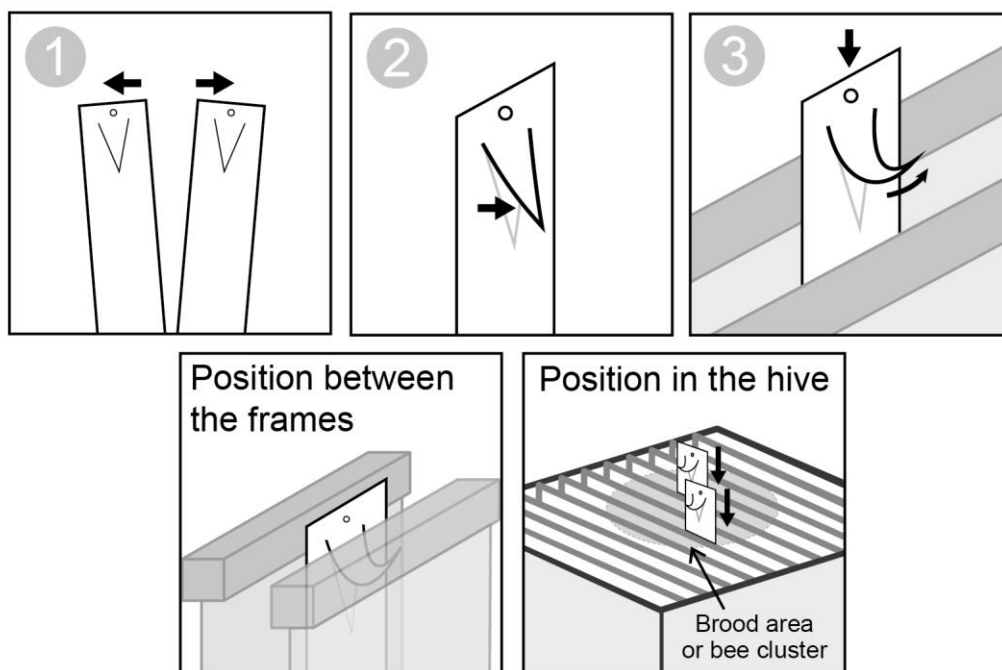
### 3.9 Administration routes and dosage

In-hive use.

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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### **3.12 Withdrawal periods**

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.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP53AD01.

### **4.2 Pharmacodynamics**

Amitraz is a formamidine acaricide that acts as an agonist on octopamine receptors causing an over-stimulation of octopaminergic synapses in acari, resulting in tremors, convulsions, detachment and death of the parasite.

### **4.3 Pharmacokinetics**

Amitraz is delivered at the surface of the strips and acts by contact with bees. The pharmacokinetics of amitraz in bees is unknown.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: use immediately and discard any unused veterinary medicinal product.

### **5.3 Special precautions for storage**

Do not store above 30°C. Store in the original package

Keep the package tightly closed.

Protect from light.

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

Heat-sealed multi-layer sachet made of two films: PE/PA/Alu/PET and PE/Alu/oPA.

Pack sizes:

4 strips

10-strips

12 strips

60-strips

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

VETO-PHARMA SAS

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

<Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}.>

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

<{MM/YYYY}>  
<{DD/MM/YYYY}>  
<{DD month YYYY}>

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription. (CZ, EL, RO, HU, NO, LT, AT, PL, SK, BG, SI, FI, CY, HR, DE)

Veterinary medicinal product not subject to prescription. (IE, BE, DK, SE, UK(NI))

Veterinary medicinal product subject to prescription except for some pack sizes. (FR)

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE** (*corresponding to the immediate packaging*)

**{STRIPS PACK}**

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

Apivar 500 mg amitraz bee-hive strips for honey bees (AT, BE, BG, CY, CZ, DE, EL, FR, HU, LT, RO, SK)

Apivar 500 mg bee-hive strips for honey bees (HR, IE, PL, SI, UK(NI))

Apivar vet 500 mg bee-hive strips (SE, NO, FI)

Apivar (DK)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 15 g strip contains:

Amitraz ..... 500 mg

**3. PACKAGE SIZE**

4 strips

10 strips

12 strips

60 strips

Not all pack sizes may be marketed.

**4. TARGET SPECIES**

Honey bees – *Apis mellifera*.

**5. INDICATIONS**

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

For products not subject to veterinary prescription.

**6. ROUTES OF ADMINISTRATION**

In-hive use.

**7. WITHDRAWAL PERIODS**

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.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30 °C.

Store in the original strips package.

Keep the strips package tightly closed.

Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VETO-PHARMA SAS

**14. MARKETING AUTHORISATION NUMBERS****15. BATCH NUMBER**

Lot

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Apivar 500 mg amitraz bee-hive strips for honey bees (AT, BE, BG, CY, CZ, DE, EL, FR, HU, LT, RO, SK)

Apivar 500 mg bee-hive strips for honey bees (HR, IE, PL, SI, UK(NI))

Apivar vet 500 mg bee-hive strips (SE, NO, FI)

Apivar (DK)

### 2. Composition

Each 15 g strip contains:

Active substance

Amitraz..... 500 mg

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

“Apivar” inscription on the edge of each strip.

Strips are attached by two with a pre-cut line.

### 3. Target species

Honey bees – *Apis mellifera*.

### 4. Indications for use

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. Special warnings

Special warnings:

It is recommended not to use the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product should be based on results of susceptibility testing, and it is recommended to seek advice from your veterinarian or local bee inspector.

Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary medicinal product.

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

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

Keep children away during application of the veterinary medicinal product.

Wash hands after use.

Do not inhale or ingest.

Special precautions for the protection of the environment:

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

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 veterinary medicinal product at the same time.

Overdose:

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.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

None known.

**7. Adverse events**

Honey bees.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorder <sup>1</sup>
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<sup>1</sup>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 veterinary medicinal product, per se.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local

representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

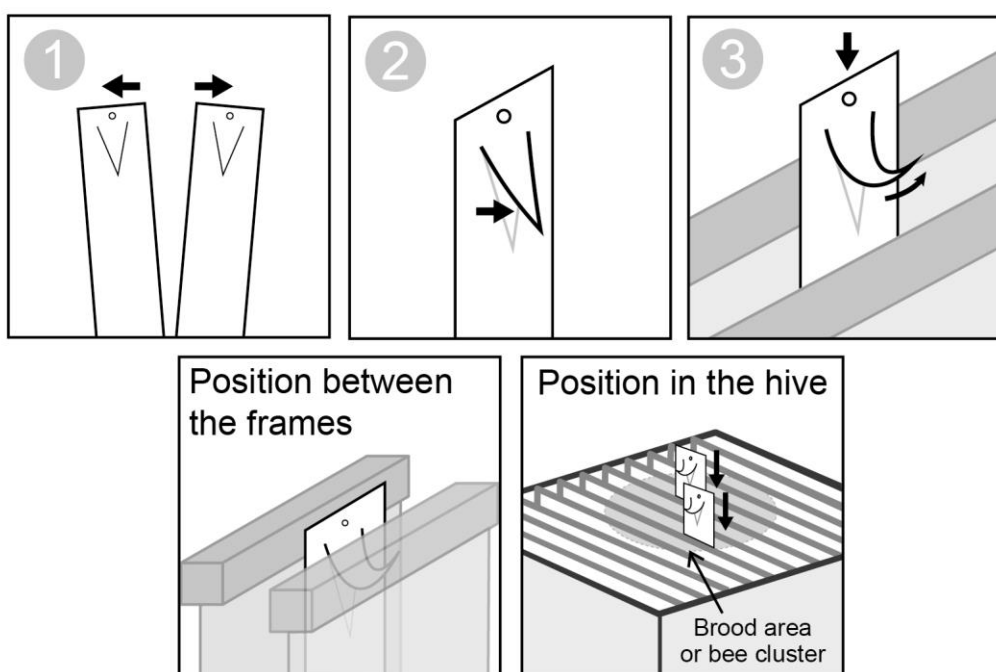
## 8. Dosage for each species, routes and method of administration

In-hive use.

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 periods

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**

Keep out of the sight and reach of children.  
Do not store above 30 °C.  
Store in the original package  
Keep the pack tightly closed  
Protect from light.

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

Shelf life after first opening the immediate packaging: use immediately and discard any unused veterinary medicinal product.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.  
The veterinary medicinal product should not enter watercourses as Amitraz may be dangerous for fish and aquatic organisms.  
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

#### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription. (CZ, EL, RO, HU, NO, LT, AT, PL, SK, BG, SI, FI, CY, HR, DE)

Veterinary medicinal product not subject to prescription. (IE, BE, DK, SE, UK(NI))

Veterinary medicinal product subject to prescription except for some pack sizes. (FR)

#### **14. Marketing authorisation numbers and pack sizes**

MA number

Pack sizes:

4 strips

10 strips

12 strips

60 strips

Not all pack sizes may be marketed.

#### **15. Date on which the package leaflet was last revised**

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

## **16. Contact details**

### Marketing authorisation holder :

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

### Manufacturer responsible for batch release:

VETO-PHARMA  
ZA Champrue  
36310 Chaillac  
FRANCE

### Local representatives and contact details to report suspected adverse reactions:

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

#### **België/Belgique/Belgien**

Fendigo NV  
Herrmann Debrouxlaan 17 B-1160 Brussels  
BE-1160 {Brussels}  
Tél/Tel: + 32 2 734 48 21

#### **Република България**

BioMarketing Bulgaria Ltd  
Topli Dol Street, N°4  
BG 1680 Sofia  
Тел: + 359 899 181 855

#### **Danmark**

#### **Deutschland**

Wirtschaftsgenossenschaft deutscher Tierärzte  
e.g WDT  
Siemensstr. 14  
DE-30827 Garbsen  
Tel: + 491725152226

#### **Ελλάδα**

Kyrka Evangelia & CO LTD  
69 Olimpionikon  
EL-15 354 str-Glikanera Attiki  
Τηλ: + 30 210 6610771

#### **France**

VETO-PHARMA SAS  
12-14 Rue de la Croix Martre  
FR-91120 Palaiseau  
Tél:  
pv@vetopharma.com

#### **Lietuva**

BICIU AUSTEJA LTD  
Saltupio str. 24Anyksčiai LT29109 Lithuania  
LT 29109 Lithuania Anyksčiai  
Tel: +37069918861

#### **Česká republika**

M+H s.r.o.  
Λονδύνσκζ 730/59  
CZ 12000 ΠΡΑΧΑ 2  
Tel: +420 731 616 900

#### **Magyarország**

AlphaVet Kft.  
Hofherr Albert 42  
HU-0000 1194 Budapest  
Tel.: + 36 22 534 500

#### **Norge**

#### **Österreich**

Prozoon Pharma GMBH  
Karl-Schönherr-Strabe,3  
A-4600 Wels  
Tel: + 43 7242 283 33

#### **Polska**

Vet-Animal sp z.o.o  
Ul Lubichowska 126  
PL – 83-200 Starogard Gdanski  
Tel.: + 48 608 145 439

**Hrvatska**

Mount trade d.o.o  
Industrijska 13,  
43280 Garesnica  
Tel: +385914859141

**Ireland****Slovenská republika**

KAROL MESZAROS - MEDE  
MALY LEG167  
SK-93037 Lehnice  
Tel: + 421 907 158 888

**Κύπρος**

Cycon Chemicals Ltd  
<{ Erecthiou 1, Engomi }  
CY-000 00 2413 - Nicosia  
Τηλ: + 357 99563223

**United Kingdom (Northern Ireland)**

EH Thorne (BeeHive) LTD  
Beehive Business Park  
Rand, UK, LN8 5UJ  
Tel: +441613858555

**România**

SC UNICUB GRUP SRL – Ferma Apicola  
Merisani  
Codrului st No. 16. Magurele Ilfov  
077125 – RO  
Tel: + 40(0)745383789

**Slovenija**

Vetconsult pharma d.o.o  
Gerbiceva 50  
SI-1000 Ljubljana, Slovenia  
Tel: + 386 1 280 06 70

**Suomi/Finland****Sverige**