

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apivar 500 mg bee-hive strips for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 g strip contains:

Active substance : Amitraz 500 mg

Excipient :

Qualitative composition of excipients and other constituents
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Ethylene vinyl acetate

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 ¹
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¹A 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.

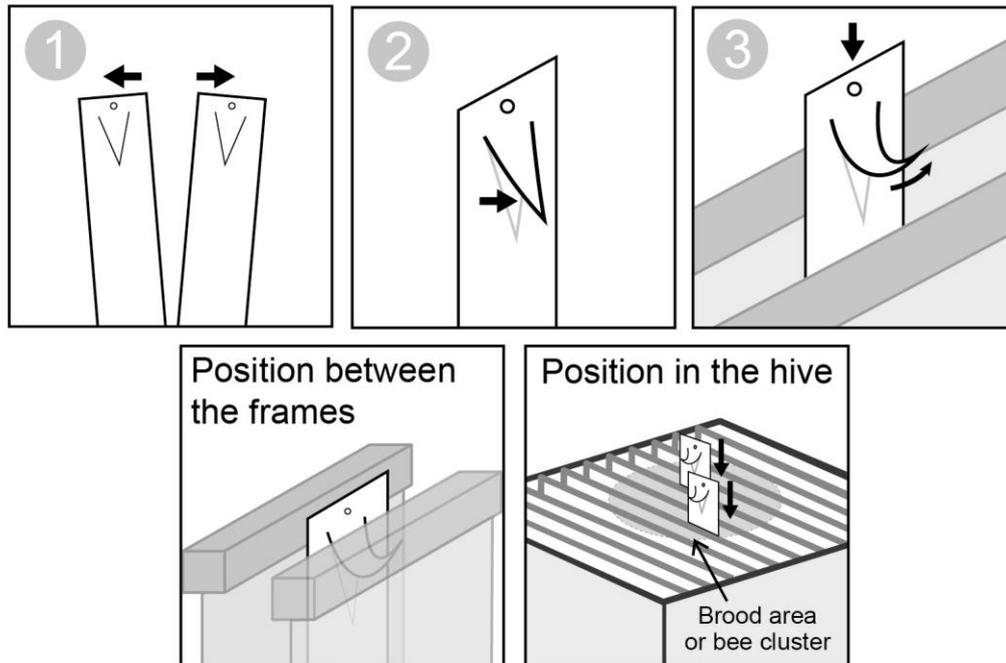
3.9 Administration routes and dosage

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)

VPA22827/001/001

8. DATE OF FIRST AUTHORISATION

26 September 2017

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

13 December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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>).