SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apivar 500 mg bee-hive strips for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15g strip contains:

Active substance: Amitraz 500 mg

Excipient:

Qualitative composition of excipients and other constituents
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

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 destructo*r

3.3 Contraindications

None.

3.4 Special warnings

Do not use the product during the honey flow or in the presence of supers. The product can product can be used after the honey harvest. See section “Amount to be administered and administration route”.
Do not cut the strips.
Treat all colonies in an apiary simultaneously.
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.

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 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 of 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 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]

[1]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.

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

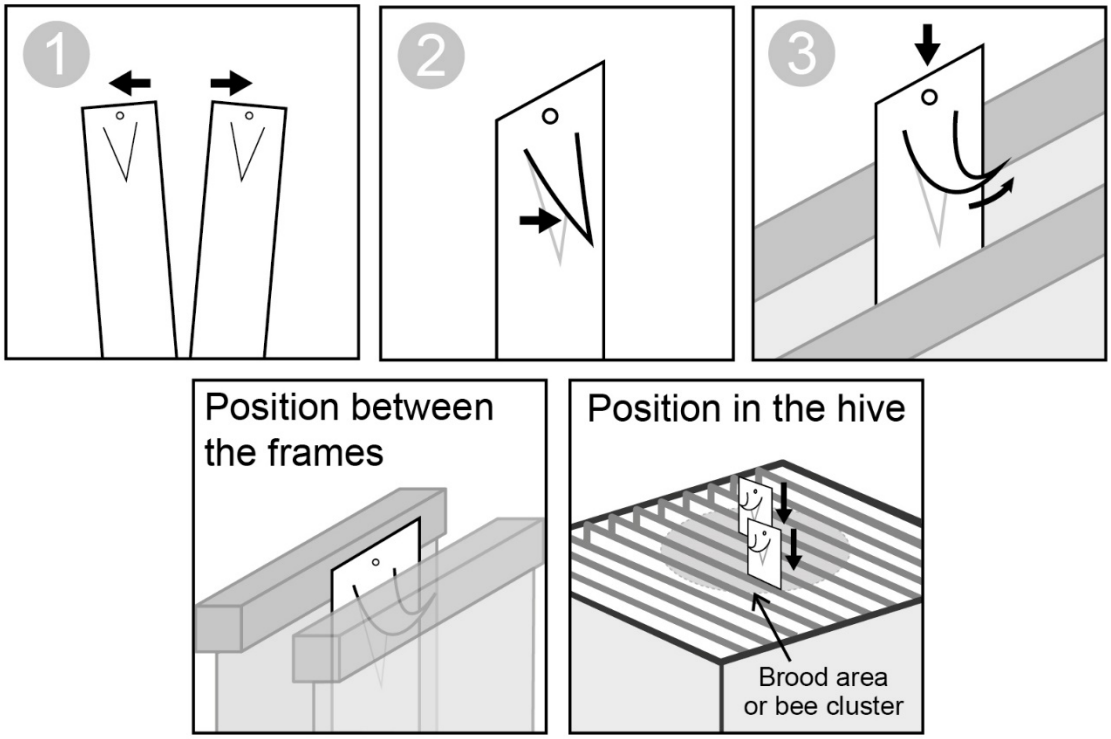
Not applicable

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 product at the same time.

3.9 Administration routes and dosage

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 product must not be administered when honey supers are present. The product can be used 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.
Colonies can be fed during treatment to stimulate activity and encourage contact with the strips.

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

The product should be part of an integrated varroa control programme and treatment rotations should be applied.
Bee colonies should be monitored routinely for the level of varroa mite infestation in order to inform what, and when, control methods should be used.

Inappropriate use of the product could result in increased risk of resistance development and could ultimately result in ineffective therapy.
The success of treatment should be monitored during treatment and for a period thereafter.
In case of suspicion of amitraz resistance, the use of the product should be ideally based on the results of sensitivity tests.

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.
Amitraz can accumulate in wax; Brood combs should be replaced with new foundation at least every three years. Do not recycle brood frames as honey frames.

4. <PHARMACOLOGICAL> <IMMUNOLOGICAL> 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.
Resistance to amitraz in *Varroa destructor* is associated with mutations in the β-adrenergic-like octopamine receptor.

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.

4.4 Environmental properties
Amitraz may be dangerous for fish and other aquatic organisms.

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 product.

5.3 Special precautions for storage

Do not store above 30°C
Store in the original strips package.
Keep the strips package tightly closed. Protect from light.

5.4 Nature and composition of immediate packaging

Heat-sealed sachet made of low density polyethylene / oriented polyamide / aluminum / polyethylene terephthalate.
4 strips pack size
10-strip pack size
12 strips pack size
60-strip pack size
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

Vm 51567/5000

8. DATE OF FIRST AUTHORISATION

15 September 2017

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

March 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 05 June 2025