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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee-hive strips.
Rectangular translucent homogeneous rigid strip with a V-shape cutting at one end and a hole above. Strips are attached by two with a pre-cut line.

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in case of known resistance to amitraz.

4.4 Special warnings for each target species

Do not use the product during the honey flow or in the presence of supers. The 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.

4.5 Special precautions for use

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.
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.

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.

4.6 Adverse reactions (frequency and seriousness)

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:
https://www.gov.uk/report-veterinary-medicine-problem

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

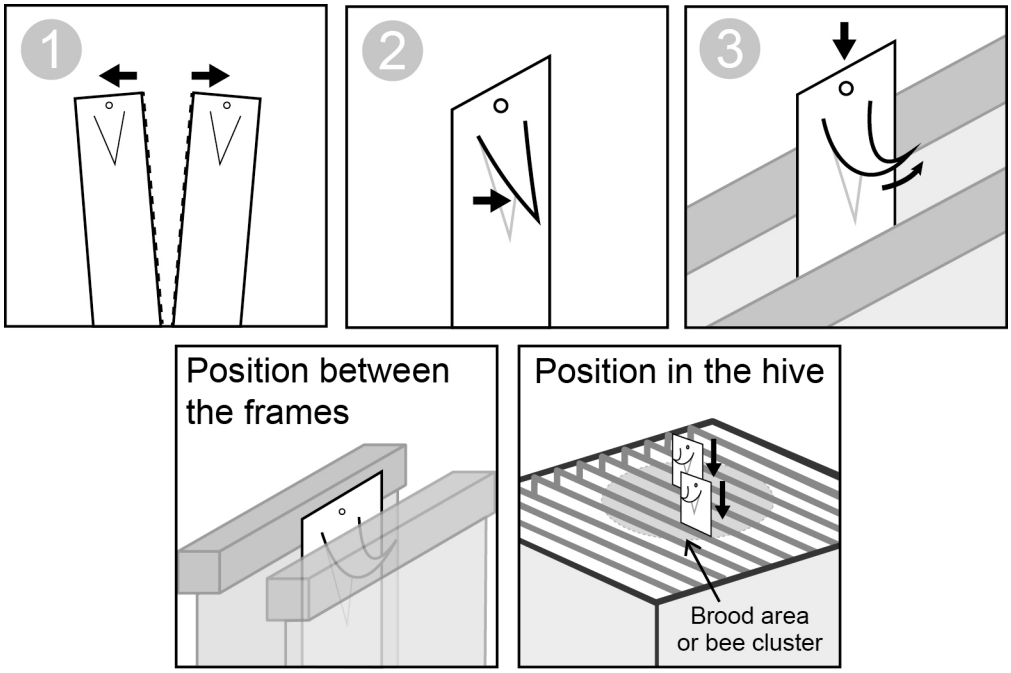
The toxicity of amitraz is increased in the presence of copper salts and the therapeutic activity is reduced in the presence of piperonyl butoxide. The concomitant use of these substances with amitraz should be avoided.
Do not use any other parasiticide product at the same time.

4.9 Amounts to be administered and administration route

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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 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.
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.

5. PHARMACOLOGICALPROPERTIES

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents
ATC-vet code: QP53AD01.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylene vinyl acetate

6.2 Major incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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.

7. MARKETING AUTHORISATION HOLDER

Veto-Pharma SAS
12-14 Rue de la Croix Martre
F-91120 Palaiseau
France

8. MARKETING AUTHORISATION NUMBER

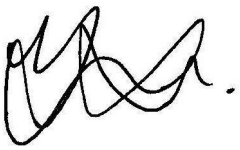
Vm 51567/5000

9. DATE OF FIRST AUTHORISATION

15 September 2017

10. DATE OF REVISION OF THE TEXT

March 2022



Approved: 02 March 2022