SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

APISTAN 10.3% w/w bee hive strip [UK]
Apistan vet 10,3% bikupestrip [SE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	mg/strip
Tau fluvalinate	824

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee hive strip
8g polymer strip measuring approximately 25 x 3 x 0.075 cm.

4. CLINICAL PARTICULARS

4.1 Target species

The honeybee, *Apis mellifera* (L.)

4.2 Indications for use, specifying the target species

Control of varroosis (*Varroa destructor* (formerly known as *Varroa jacobsoni*)) in honeybee colonies.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

Tau-fluvalinate resistance has been observed in some populations of *Varroa*. Therefore, where feasible, it is recommended to conduct appropriate testing (eg. Vita/NBU test or Beltsville test) to determine whether resistant mites are present prior to treating the colony.

It is recommended to monitor mite-fall before and after administration of the product to determine the effectiveness of the treatment, particularly when it has not been possible to conduct resistance testing prior to the treatment of the colony.
It is not recommended to use the product in colonies where mites are known to be resistant to another pyrethroid treatment (e.g. flumethrin), since cross-resistance typically occurs.

The product should be used as part of an Integrated Pest Management programme. It is recommended to alternate use with non-pyrethroid varroacides where possible.

4.5 Special precautions for use

Special precautions for use in animals

Tau-fluvalinate is a lipophilic compound which can accumulate in wax over repeated administrations. Therefore brood frames should be replaced with new foundation on a regular basis to avoid accumulation of residues. In addition, wax from treated colonies must not be recycled for use as foundation in brood or honey frames. See also section 4.11.
If signs of disease appear or persist then consult your veterinary surgeon or local bee inspector.

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

This product can cause skin and eye irritation.
Avoid contact with skin, mouth and eyes.
Wear gloves when handling strips.
Wash hands thoroughly with soap and water after handling strips or contaminated clothing.
Do not smoke, drink or eat during application.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dose:
2 Apistan vet strips per brood chamber per beehive.

Administration:
Strips are suspended mid-way between the brood frames so that the bees can walk on both sides of the strip. One strip is suspended between frames 3 & 4 and the other between frames 7 & 8 within the brood chamber.
Treatment duration 6-8 weeks, after which time the strips must be removed and disposed of. The strips should not be removed from the hive for at least 6 weeks. Do not leave the strips in the hive for more than 8 weeks. The treatment period should be kept as short as possible in order to reduce the likelihood of trace residues in brood wax and to avoid the development of mite resistance.

Small and wintering bee colonies and nuclei require one strip only, suspended through the bee or brood cluster.

Strips should not be placed in the honey supers.

The efficacy is maximised if the product is used in late summer after the main honey harvest (when the amount of bee brood present is diminishing). However, in the case of severe infestations, Apistan vet can be used at any time of year.

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

No treatment specified. In case of doubt, remove product from the colony.

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.
To avoid accumulation of residues in wax, brood frames should be replaced with new foundation on regular basis.
Do not recycle wax from treated colonies for use as foundation in brood or honey frames.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Antiparasitic products, insecticides and repellents, Ectoparasiticides, including insecticides and repellents, Ectoparasiticides for topical use, including insecticides, Pyrethrins and pyrethroids, tau-fluvalinate.

ATC vet code: QP53AC10

5.1 Pharmacodynamic properties

Tau-fluvalinate is an ectoparasiticide of the cyano-pyrethroid class of compounds, which act by causing rapid depolarisation of the axonal membranes. The molecule is of low toxicity to honeybees in particular due to the poor fit of the molecule in potential receptor sites in this species. In *Varroa destructor*, uptake is rapid and death results from hyper-excitability and nervous exhaustion.
Tau-fluvalinate acts by contact. Molecules of the Active Pharmaceutical Ingredient migrate to the strip surface at a proscribed rate, determined by the reservoir loading of the polymer. Bees walk over the strips and pick up surface molecules of tau-fluvalinate. *Varroa* mites in contact with the bees are subjected to the molecule, which is lethal to mites but of relatively low hazard to bees.

The resistance mechanisms of *Varroa* mites to tau-fluvalinate can be explained by an increased detoxification due to the monooxygenases in the P450 system. Oxygenases appear to be important for the resistance of *Varroa* mites to tau-fluvalinate, whereas the influence of esterases appears to be negligible. Other mechanisms, such as the reduced uptake of active substance or modification of the binding site, could also be involved.

5.2 Pharmacokinetic particulars

Although the target species for Apistan vet is the honeybee, the product acts directly upon the *Varroa* mites associated with the bees. There are no known pharmacokinetic effects in the bees.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinylchloride
Bis (2-ethylhexyl) phthalate
Butylbenzyl phthalate
Epoxidized soybean oil
Stearic acid

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

Keep strips in original, unopened packaging until ready to use
This veterinary medicinal product does not require any special temperature storage conditions
Protect from direct sunlight
Store in original packaging only
Do not store strips near pesticides or other chemical substances which could contaminate the product
Store away from foodstuffs
Replace unused strips in the original packaging
Use strips for one treatment only - do not re-use strips

6.5 Nature and composition of immediate packaging

Interior laminated foil pouch holding 10 Apistan vet strips; contained in outer paper pouch bearing the product label.

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. Ask your veterinary surgeon how to dispose of medicines no longer required. This product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Medicines should not be disposed of via wastewater. These measures should help to protect the environment.

EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the strips or empty packaging.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2018-12-20