

APISTAN

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apistan 10.3% w/w bee hive strip [UK]
Apistan vet 10.3% w/w bee hive strip [SE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	mg/strip
Tau fluvalinate	824

For a full list of excipients, please 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*

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

None

4.5 Special precautions for use

i. Special precautions for use in animals

If signs of disease appear or persist then consult your veterinary surgeon.

- ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid contact with skin, mouth and eyes.
Wear gloves when handling strips.
Wash hands thoroughly after handling strips.
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 Amount(s) to be administered and administration route

Dose:

2 Apistan 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 broodwax 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 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

Honey - Zero days
Do not use during honey flow.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antiparasitic products, insecticides and repellents, Ectoparasiticides, including insecticides and repellents, Ectoparasiticides for topical use, including insecticides, Pyrethrins and pyrethroids, fluvalinate.

ATC Vet Code: QP53AC10

5.1 Pharmacodynamic properties

Tau-fluvalinate is an ectoparasiticide of the cyanopyrethroid 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 hyperexcitability and nervous exhaustion.

5.2 Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 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 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, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with strips or empty packaging.

7. MARKETING AUTHORISATION HOLDER

Vita (Europe) Limited
Vita House
London Street
Basingstoke
Hampshire
RG21 7PG

8. MARKETING AUTHORISATION NUMBER

Vm 17017/4000

9. DATE OF FIRST AUTHORISATION

Date: 26 November 1998

10. DATE OF REVISION OF THE TEXT

Date: November 2014