A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

(Pouch Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

APISTAN 10.3% w/w bee hive strip

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tau-fluvalinate 824 mg

3. PHARMACEUTICAL FORM

Bee hive strip

4. PACKAGE SIZE

10 polymer bee hive strips. Each 8g strip containing 824mg tau-fluvalinate.

5. TARGET SPECIES

Honeybees

6. INDICATION(S)

Varroa control for bees.

APISTAN is a slow release polymer strip formulation for the control of the parasitic mite *Varroa destructor* (formerly known as *Varroa jacobsoni*) on honeybees.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage instruction
2 APISTAN strips per brood chamber per beehive.

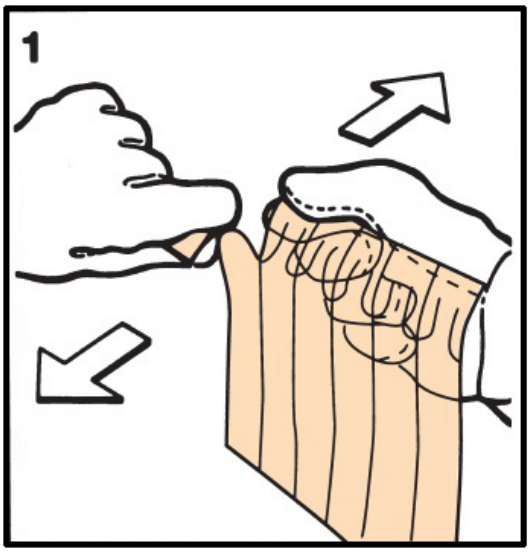
Administration:
Suspend strips mid-way between the brood frames so that the bees can walk on both sides of the strip. One strip is suspended between frames 3 & 4 and the other between frames 7 & 8 within the brood chamber.
Small and wintering bee colonies and nuclei require one strip only suspended near the centre of the brood chamber. Do not place strips in the honey supers.

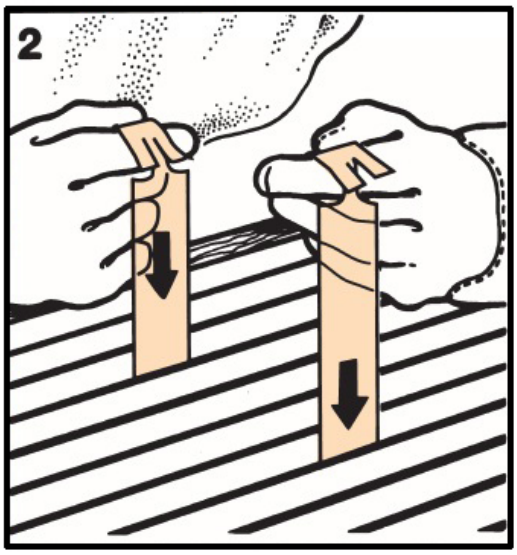
Duration of use
Treatment duration is 6–8 weeks after which time the strips are removed and disposed of. The strips should not be removed from the hive for at least 6 weeks. Do not leave the strips in the hive for more than 8 weeks. The treatment period should be kept as short as possible in order to reduce the likelihood of trace residues in the brood wax and to avoid the

development of mite resistance. If signs of disease persist or appear consult your veterinary surgeon or local bee inspector.

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

DIRECTIONS FOR USE
Method of Application
Read USER WARNINGS below, before handling the medicinal product.
The strips are bonded together in one sheet.
To separate them, hold firmly at corner (see illustration 1), near top and pull along scored line from top to bottom. Replace the unused strips in the original package.
APISTAN strips are suspended in the brood chamber (hive body) in such a way that the bees can walk on both sides of the strips. To suspend the strips between the frames, twist out the wings of each strip (see illustration 2).





8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

USER WARNINGS
This product can cause skin and eye irritation.
Wear gloves when handling strips.

Avoid contact with skin, mouth and eyes.
Wash hands thoroughly with soap and water after handling strips or contaminated clothing.
Do not smoke, drink or eat during application

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.

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.

10. EXPIRY DATE

Expiry date: See side of pouch.

11. SPECIAL STORAGE CONDITIONS

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 strips.
Replace any unused strips in the original packaging.
Store away from foodstuffs.
Use strips for one treatment only; do not re-use strips.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
Legal category:
AVM-GSL

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Vita (Europe) Ltd
Vita House
London Street
Basingstoke
Hampshire
RG21 7PG
United Kingdom

Additional manufacturer responsible for batch release:
Pharmapac Limited
Unit D1,
Willow Drive,
Naas Enterprise Park,
Newhall,
Naas,
Co. Kildare, W91 E797,
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 17017/4000

17. MANUFACTURER'S BATCH NUMBER

Batch number: See side of pouch.

Approved 10 September 2021