

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Apistan vet 10,3% bikupestrip
SE [RMS] only (No leaflet for UK [CMS])

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

Marketing authorisation holder:

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

Manufacturers responsible for batch release:

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

Pharmapac Limited
Unit D1,
Willow Drive,
Naas Enterprise Park,
Newhall,
Naas,
Co. Kildare, W91 E797,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apistan vet 10,3% bikupestrip [SE]

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Tau-fluvalinate 824 mg

4. INDICATION(S)

Varroa control for bees

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

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

None known.

7. TARGET SPECIES

Honeybees

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage instruction

2 Apistan vet 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.

Apistan vet 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 vet can be used at any time of year.

9. ADVICE ON CORRECT ADMINISTRATION

DIRECTIONS FOR USE

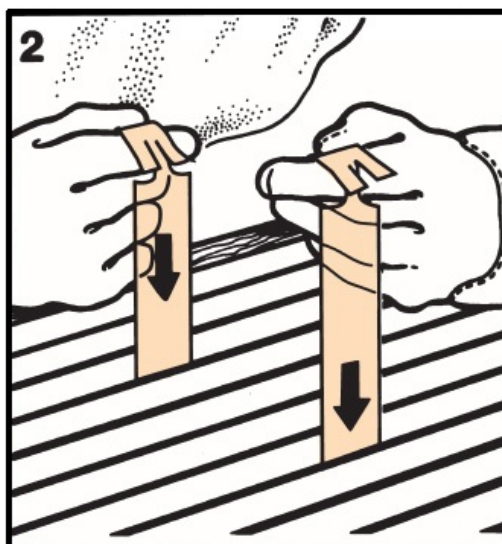
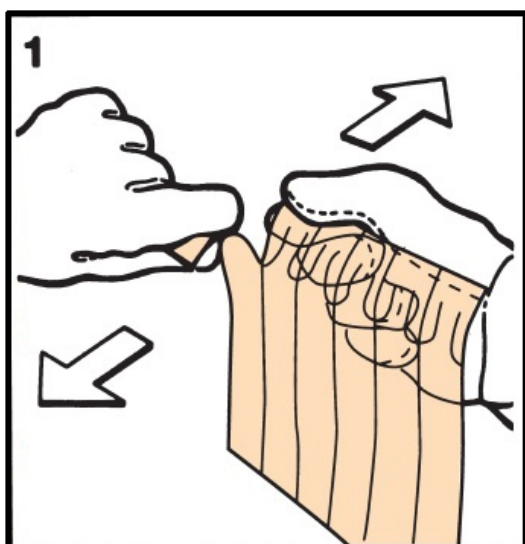
Method of Application

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 vet 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).



10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep strips in original, unopened packaging until ready to use.

This veterinary medicinal product does not require any special temperature storage condition.

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 WARNING(S)

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2021-08-24