ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

**{Multilayer sachet containing 10 strips of 300 mm x 40 mm,
Multilayer sachet containing 10 strips of 250 mm x 48 mm}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apitraz 500 mg bee-hive strips for honey bees

2. COMPOSITION

Each 27.6 g strip contains:

Active substance:

Amitraz: 500 mg

White rectangular plastic strip with two tabs and a marker fold line.

3. PACKAGE SIZE

10 strips (300 mm x 40 mm)
10 strips (250 mm x 48 mm)

4. TARGET SPECIES

Honey bees – *Apis mellifera*

5. INDICATIONS FOR USE

Indications for use
Treatment of external parasitosis in honey bees caused by *Varroa destructor*.

6. CONTRAINDICATIONS

Contraindications
None

7. SPECIAL WARNINGS

Special warnings
Special warnings:

All colonies in the same apiary should be treated simultaneously to avoid reinfestation by robbery.

Do not re-use the strips.

It is recommended not to use the product before the end of the honey producing season of the year. See also ”10. Advice on correct administration” and “11. Withdrawal periods”.

Bee colonies should be monitored routinely for the level of varroa mite infestation during treatment and also for a period thereafter.

The product should be used as part of an integrated varroa control program.

Inappropriate use of the product could result in an increased risk of resistance development and could ultimately result in ineffective therapy.
Amitraz resistance has been reported in some populations of Varroa mites.
In countries with recognized amitraz resistance or in case of suspicion of amitraz resistance, the use of the product should ideally be based on results of susceptibility testing (e.g. Beltsville test). Please speak to your veterinarian or local bee inspector for further information.

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). No information is available on the safety and efficacy in hives with more than one brood chamber.

In the presence of brood and depending upon the initial infestation level, an adequate mite reduction above 95% is expected to occur at the end of the 10-weeks of treatment.

Special precautions for safe use in the target species:

The safety profile for the product has not been established in weak colonies, i.e. those colonies containing a number of bees that is lower than expected for the time of year.

Do not exceed or reduce the recommended dose and recommended duration of use.

Remove the strips at the end of treatment.

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

This veterinary medicinal product contains amitraz, which can lead to neurological side-effects in humans.

Amitraz is a monoamine oxidase inhibitor (MAOI); therefore, people taking MAOI-containing medication should take particular care.

Handle and open container with care to minimise the potential for inhalation.

This veterinary medicinal product may cause skin sensitisation, allergic reactions and eye irritation.

Personal protective equipment consisting of impervious gloves and the usual beekeeping protective clothing should be worn when handling the veterinary medicinal product.

Avoid contact with skin. In case of contamination, wash thoroughly with soap and water.

Avoid contact with eyes. In case of contact, rinse with plenty of water immediately. If irritation occurs, seek immediate medical advice and show the package leaflet or label to the physician.

Do not eat, drink or smoke during its use.

Wash your hands thoroughly after use.

In case of accidental ingestion or inhalation, seek medical advice immediately and show the label to the physician.

Special precautions for the protection of the environment:

Do not throw strips or empty sachets in ponds or streams, as the product could be dangerous for fish and aquatic organisms.

Interactions with other medicinal products and other forms of interaction:

The toxicological effect of the amitraz is increased in the presence of copper salts and the therapeutic activity decreases in the presence of piperonyl butoxide. Use of either of these substances with the product should be avoided.

Do not use any other parasiticide product at the same time.

Overdose:

One and half times the recommended dose, for a period of 8 weeks has been administered and results in a slightly higher number of dead bees compared to the recommended posology.

No overdose studies have been conducted when the product is applied for 10 weeks.

8. ADVERSE EVENTS

Adverse events
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system <{national system details}>.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In-hive use

Use two strips per hive (i.e. 1 g of amitraz per hive), and hang each strip between two frames of honeycomb inside the brood area or the bee cluster with a minimum distance of two frames between strips.

Place the strips between frames where the bees exhibit the greatest mobility. Hang the strips in such a way as to provide bees with free access to both sides, whilst maintaining bee space.

Hive types:
- Hives type Dadant (Strips of 300 mm x 40 mm), place one strip between the third and the fourth honeycombs and the other between the seventh and eighth honeycombs.
- Hives type Layens (Strips of 300 mm x 40 mm), place one strip between the fifth and sixth honeycombs and the other between the ninth and tenth honeycombs.
- Hives type Langstroth (Strips of 250 mm x 48 mm), place one strip between the third and the fourth honeycombs and the other between the seventh and eighth honeycombs.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

In the absence of brood or when the amount of brood is at its lowest level, strips may be removed after 6 weeks of treatment. In the presence of brood, strips must only be removed after 10 weeks of treatment.

The strips should not be cut.

Strips should be repositioned, if necessary, in case of changes in the bee cluster or brood area.

Precautions of use and application timetable:

The recommended time for treatment is when honey supers are not present after the last honey harvest (late summer/autumn) and before spring honey-flow period. Infestation monitoring is recommended to determine the best time for treatment. Remove the strips before the honey flow starts.

Levels of brood and climatic conditions must be considered prior to product application.
The product should be applied when the bees are still active, i.e. before the bees form a winter cluster, the exact timing of which can vary between climatic zones.

11. WITHDRAWAL PERIODS

Withdrawal periods

Honey: zero days

Do not use during honey flow. Do not extract honey from the brood chamber.

Do not harvest honey during the 6-week or 10-week treatment period.

Brood combs should be replaced with new foundation at least every three years. Do not recycle brood frames as honey frames.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25ºC

Do not use this veterinary medicinal product after the expiry date which is stated on the combined label and leaflet after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packeging: Use immediately

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal
Medicines should not be disposed of via wastewater <or household waste>.

This veterinary medicinal product should not enter water courses as amitraz may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 20634/3000

Pack sizes

Sachet containing 10 strips of 300 mm x 40 mm
Sachet containing 10 strips of 250 mm x 48 mm.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

March 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and <manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Laboratorios Calier, S.A.
C/ Barcelonès 26 (Pla del Ramassà)
08520 Les Franqueses del Vallès
Barcelona
Spain

Manufacturer responsible for batch release:
Laboratorios Calier S.A.
C/ Barcelones 26
Poligono Industrial El Ramassa
Les Franqueses del Valles
Barcelona
08520 Spain

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Once opened use immediately.

21. BATCH NUMBER

Lot {number}

Approved 28 April 2023