

B. LABEL – LEAFLET PACKAGE

LABEL- PACKAGE LEAFLET

1. 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:

LABORATORIOS CALIER, S.A.
Barcelonès, 26 – Pla del Ramassà
Les Franqueses del Vallès
(Barcelona), Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

APITRAZ 500 mg bee-hive strips for honey bees
Amitraz

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

Each 27.6 g strip contains:

Active substance:

Amitraz500 mg

PHARMACEUTICAL FORM

Bee-hive strip

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

4. INDICATION

Treatment of external parasitosis in honey bees caused by *Varroa destructor* sensitive to amitraz.

5. CONTRAINDICATIONS

Do not use in the case of known resistance to amitraz.

6. ADVERSE REACTIONS

None known

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon or a local representative of the marketing authorisation holder

7. TARGET SPECIES

Honey bees – *Apis mellifera*

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

In-hive use

Use two strips per hive, (i.e. 1 g of amitraz per hive) hang each between two frames of honeycomb food stores.

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, place one strip between the third and the fourth honeycombs and the other between the seventh and eighth honeycombs.

- Hives type Layens, place one strip between the fifth and sixth honeycombs and the other between the ninth and tenth honeycombs.

9. ADVICE ON CORRECT ADMINISTRATION

Strips must be removed after 6 weeks.

The strips should not be cut.

The product should be used when the amount of brood is low relative to peak levels. In addition, 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. Therefore, levels of brood and climatic conditions must be considered prior to product application.

10. WITHDRAWAL PERIOD

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 treatment period

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C

Shelf-life after first opening the container: Use immediately

Do not use if you notice description of the visible signs of deterioration

12. SPECIAL WARNING(S)

Special warnings for each target species

All colonies in the same apiary should be treated simultaneously to avoid 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 section 9. Advice on correct administration.

Inappropriate use of the product could result in an increased risk of resistance development and could ultimately result in ineffective therapy.

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 programme.

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.

Special precautions for use in animals

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.

Keep children well away during application of product.

Wash your hands thoroughly after use.

Do not inhale or ingest

Other precautions

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

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

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.

Interaction 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

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

14. DATE ON WHICH THE LABEL-LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:

Multilayer sachet containing 10 strips of 300 mm x 40 mm

Multilayer sachet containing 10 strips of 250 mm x 48 mm.

For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Batch:

EXP:

Reg. n°: