

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apitraz 500 mg bee-hive strips for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 27.6 g strip contains:

Active substance:

Amitraz..... 500 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee-hive strip

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

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees – *Apis mellifera*

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 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 4.9: Precautions of use and application timetable.

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.

4.5 Special precautions for use

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 contact, 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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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.

4.9 Amounts to be administered and administration route

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.

Strips must be removed after 6 weeks.

The strips should not be cut.

Precautions of use and application timetable:

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.

4.10 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.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides, for topical use, incl. insecticides, Amidines. ATCvet code: QP53AD01

5.1 Pharmacodynamic properties

Amitraz is a parasiticide belonging to the formamidine group of insecticides.

Amitraz has a neurotoxic action. The principal mode of action is interaction with octopamine receptors in the central nervous system (CNS) of ectoparasites which induces increased neuronal activity, abnormal behavior, detachment and death.

5.2 Pharmacokinetic particulars

Contact between the bees and the amitraz strip impregnates the varroa outer cuticle and consequently amitraz acts against this mite.

The kinetics of amitraz is unknown in bees.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poly(ethylene-vinyl acetate)

Styrene-Butadiene block copolymer

Paraffin liquid

Calcium magnesium carbonate

Pentaerythrityltetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]

Didodecyl 3,3'thiodipropionate

Erucamide

Ultra-high molecular weight Siloxane polymer, dispersed in polypropylene homopolymer

6.2 Major Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf-life after first opening the immediate packaging: Use immediately.

6.4. Special precautions for storage

Do not store above 25° C.

6.5 Nature and composition of immediate packaging

Multilayer sachet consisting of 4 layered foil arranged as follows: (outer layer) PET/ LDPE/aluminium foil/ thermoplastic resin coating (inner layer), closed by thermoseal.

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

The veterinary medicinal product should not enter watercourses as this may be dangerous for fish and aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE