

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

THYMOVAR 15 g bee-hive strips for honey bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One bee-hive strip contains:

Active substance: 15 g thymol

3. PHARMACEUTICAL FORM

Bee-hive strip

Medicated cellulose sponge cloth (yellow wafer of 50 x 145 x 4.3 mm)

4. CLINICAL PARTICULARS

4.1 Target species

Honey bee (*Apis mellifera*)

4.2 Indications for use, specifying the target species

Treatment of varroosis on honey bee (*Apis mellifera*) due to Varroa mite (*Varroa destructor*).

4.3 Contraindications

Do not use when maximum daytime temperature is **above 30 °C**.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

If applied right before or during honey flow, residues in the honey may be increased. No sufficient efficacy can be expected if the average outside temperature is below 15 °C.

All colonies in the same apiary (location) should be treated simultaneously to avoid robbery.

Never place bee-hive strips near a sugar feeder as this may reduce feeding.

Do not apply if outside temperatures exceed 30 °C. Treatment at temperatures above of 30 °C leads to increased stress and mortality of adult bees and brood.

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

Because of possible contact dermatitis and irritation of the skin and eyes, direct skin and eye contact should be avoided. In case of skin contact wash thoroughly the affected area with soap and water. In case of eye contact wash the eyes thoroughly with copious amounts of clean running water and seek medical advice. When handling the product, wear impermeable gloves as well as the usual protection equipment.

Do not treat during honey flow to avoid potential taste tainting.

4.6 Adverse reactions (frequency and seriousness)

Bees may remove food from directly under the bee-hive strip. Brood too close to the bee-hive strip (< 4 cm) will be removed too.

A slight agitation of the colony and minor increase in mortality of the bee brood and bees during the treatment can occur at high temperatures (above 30 °C).

There may be a reduced acceptance of the food if feeding takes place at the same time as the treatment.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

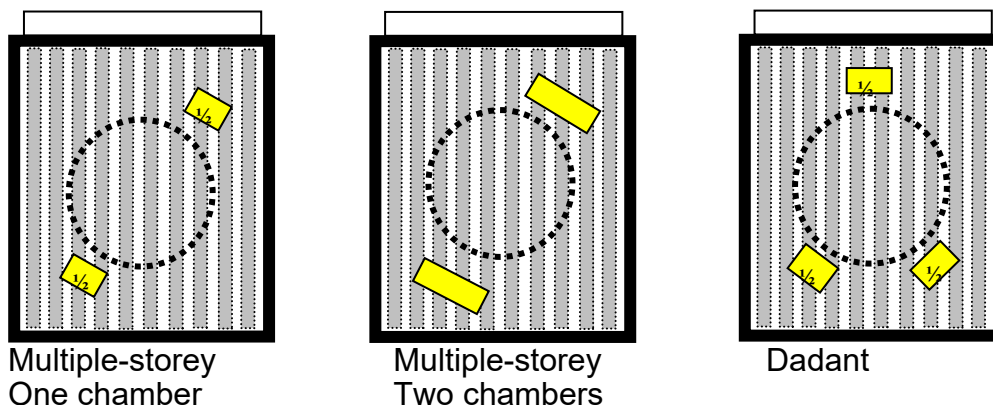
4.9 Amounts to be administered and administration route

Dosage

Hive system	THYMOVAR-bee-hive strips	
	1 st application	2 nd application
Multiple-storey (1 chamber)	1	1
Multiple-storey (2 chambers)	2	2
<i>Dadant</i>	1 ½*	1 ½*

* Bee-hive strips can be cut by a pair of scissors.

Appropriate placement of the bee-hive strips in the open hives viewed from the top.



Application

As soon as the honey supers are taken off, the first application takes place by putting 1 -2 bee-hive strips on the top bars of the combs. According to the figures and table above, the number of bee-hive strips has to be adapted to the size of the hive. In the case of a multiple storey hive (two chambers) the bee-hive strips are placed on the combs of the upper box. Bee-hive strips should be close to but not directly over open or sealed brood (preferable distance 4 cm). Ensure that there is a free space of at least 5 mm between the bee-hive strips and the hive cover. Close the hive as usual. Open floors have to be locked over the whole surface.

Remove the bee-hive strips **3-4 weeks** (21 to 28 days) **later** and put in the new bee-hive strips for the second application. Remove them after 3-4 weeks (21 to 28 days). Do not treat with THYMOVAR more than twice a year.

Temperature:

Reduced product efficacy occurs if average temperatures fall below 15 °C during the treatment. Best efficacy is achieved when maximum daytime temperatures are between 20 °C and 25 °C throughout treatment.

Integrated Pest Management

The efficacy may vary between colonies due to the surrounding conditions (temperature, reinfestation etc.). THYMOVAR should therefore be used as a treatment amongst other within an Integrated Pest Management programme, and mite drop regularly monitored. Colonies with an average mite drop of more than 1 mite per day two weeks right after the last THYMOVAR treatment have to be subjected to an additional winter or spring treatment for varroa (preferably with another active ingredient).

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

Symptoms:

The use of higher dose than recommended could lead to impetuous behaviour of the colony. Abundant dead bee and larvae (> 20) might be found in front of the hive entrance.

Emergency procedures:

Remove excess bee-hive strips of the hive.

4.11 Withdrawal period

Honey: Zero days.

Do not use before and during the collecting period of the bees (honey flow).

The combs of the brood chamber, which were present when the colony was treated with THYMOVAR, must not be extracted in the following spring.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides for topical use.

ATC vet code: QP 53 AX 22

5.1 Pharmacodynamic properties

Thymol is a phenol and naturally occurs in the essential oil fraction of many flavouring plant species.

Its exact mechanism of action is not fully understood. It may directly act on the mite through inhalation or diffusion by damaging structures at different unknown locations (the nervous system of the mite may be affected).

Through volatilisation from the bee-hive strip the thymol saturates the air in the bee hive. The thymol is inhaled or absorbed through unknown intake by the varroa mite and harms the mite.

A concentration of more than 5 µg thymol / l air in the bee hive kills the phoretic mites on the honey bees.

5.2 Pharmacokinetic particulars

The pharmacokinetics of thymol in bees is not known.

Distribution and elimination in the beehive

The 15 grams of thymol per bee-hive strip are sublimated over a period of 3-4 weeks (21 to 28 days). Appropriate sublimation of thymol takes place at temperatures between 15 °C and 30 °C.

After the removal of the bee-hive strips the vaporised residual thymol is exchanged by the natural air replacement of the colony. Residues in the wax of the combs will quickly be released out.

5.3 Environmental properties

As a natural substance thymol is rapidly metabolised and naturally decomposed in the environment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

cellulose sponge cloth

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life of veterinary medicinal product as packaged for sale: 4 years.

Shelf-life after first opening the immediate packaging:

All bee-hive strips of this sachet should be used immediately and cannot be stored further.

6.4. Special precautions for storage

Store below 30 °C

Do not refrigerate or freeze. Protect from frost.

Protect sachets from direct sunlight.

6.5 Nature and composition of immediate packaging

Sealed airtight double sachet (160 x 460 mm) of a SiO_x coated PE foil each sachet containing twice five bee-hive strips.

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 product should be disposed of in accordance with local requirements. Normally, used bee-hive strips and the sachets can be discarded as household refuse.

The product should not come into contact with water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Andermatt BioVet GmbH
Franz-Ehret-Str. 18
79541 Lörrach
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 36234/4000

9. DATE OF FIRST AUTHORISATION

15 June 2010

10. DATE OF REVISION OF THE TEXT

June 2019

Approved: 12 June 2019

