LABELLING AND PACKAGE LEAFLET

A. LABELLING

<particulars appear="" on="" outer="" package="" the="" to=""></particulars>		
{NATURE/TYPE}		
1. NAME OF THE VETERINARY MEDICINAL PRODUCT		
THYMOVAR 15 g bee-hive strips for honey bees		
Thymol.		
2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES		
15 g thymol per bee-hive strip		
3. PHARMACEUTICAL FORM		
Bee-hive strip		
4. PACKAGE SIZE		
Double-sachet with 2 x 5 bee-hive strips (= 10 bee-hive strips)		
5. TARGET SPECIES		
Honey bee		
6. INDICATION(S)		
Treatment of varroosis on honey bee		
7. METHOD AND ROUTE(S) OF ADMINISTRATION		
Read the package leaflet before use.		
8. WITHDRAWAL PERIOD		
Honey: Zero days.		
9. SPECIAL WARNING(S), IF NECESSARY		

Read the package leaflet before use.

10. EXPIRY DATE

EXP (MM.YYYY)

11. SPECIAL STORAGE CONDITIONS

Store below 30°C

Do not refrigerate or freeze. Protect from frost.

Protect sachets from direct sunlight.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36234/4000

17. MANUFACTURER'S BATCH NUMBER

Lot (A000)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

THYMOVAR

15 g thymol per bee-hive strip for honey bees

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

THYMOVAR 15 g bee-hive strips for honey bees

Thymol.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

THYMOVAR; is formulated on bee-hive strips, each containing 15 g of thymol, an essential oil allowed in food supplies.

One bee-hive strip contains:

Active substance:

15 g thymol

Pharmaceutical form:

Bee-hive strip. Medicated cellulose sponge cloth (yellow wafer of 50 x 145 x 4.3 mm)

4. INDICATION

Treatment of varroosis on honey bees due to varroa mites.

ATCvet code: QP 53 AX 22

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Honey bee (*Apis mellifera*)

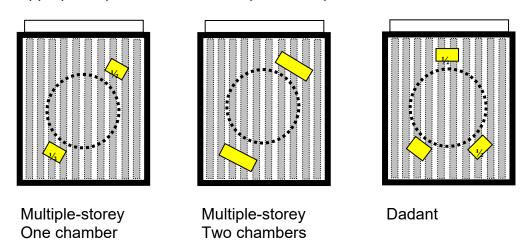
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage:

Hive system	THYMOVAR® -strips	
	1st application	2 nd application
Multiple-storey (1	1	1
chamber)		
Multiple-storey (2	2	2
chambers)		
Dadant	1 ½*	1 ½*

^{*} Strips can be cut with a pair of scissors.

Figure 1: Appropriate placement of the strips in the open hives viewed from the top.



9. ADVICE ON CORRECT ADMINISTRATION

THYMOVAR contains thymol, a volatile substance which sublimates in the air depending on temperature. On release, thymol vapour concentrations build up in the treated beehive. These vapours are highly toxic to varroa mites but concentrations are not high enough to harm the honey bees. For optimal control, appropriate concentrations of thymol vapour must be maintained for six to eight weeks.

Temperature:

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

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

Time of treatment:

The best time for THYMOVAR treatment is as soon as possible **after the last honey harvest** in late summer at recommended temperatures. Treat all hives in an apiary at the same time to avoid robbing behaviour.

Application:

Prior to THYMOVAR treatment, remove all honey supers, close or replace open or screened hive floors with solid floors, and reduce the hive entrances to normal size. It is recommended that part of the feeding is carried out before the treatment, if the infestation of varroa and the temperatures allow.

Begin the **1**st **application** of a treatment by placing appropriate number of bee-hive strips (positions shown in Fig. 1) on top of combs of the brood chamber (upper brood chamber if two). Bee-hive strips should be close to, but not directly over open or sealed brood (preferable distance > 4 cm).

Close the hive, leaving space (about 5 mm) between the bee-hive strips and the hive cover to improve the evaporation of thymol. Do not place plastic cover foils directly on the bee-hive strips.

Remove the 1st set of depleted THYMOVAR strips after 3-4 weeks.

Begin the **2**nd **application** immediately with a new set of bee-hive strips in appropriate numbers and positions, as shown in Fig. 1. Remove these bee-hive strips when they are depleted at the end of the 2nd **3-4 week** application period.

Feeding:

Never place bee-hive strips near a sugar feeder as this may reduce feeding. If the combination of sugar feeding and THYMOVAR application begins to stagnate, the colonies can be fed before the $2^{\rm nd}$ application in the following sequence: Finish $1^{\rm st}$ application by removing the bee-hive strips after 3 weeks, then place the sugar feeder into the hive and finish the feeding before inserting the bee-hive strips for the $2^{\rm nd}$ application.

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. Right after the end of the 2nd application, place a screened sticky board on the floor of the hives and monitor mite drop for a two week period. Re-treat (preferably with another active ingredient) those individual colonies where the average mite drop was greater than 1 mite per day (winter or spring treatment).

10. WITHDRAWAL PERIOD

Honey: Zero days.

Do not use before and during the collecting period of the bees (honey flow). Do not extract treated combs of the brood chamber in the following spring.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store below 30 °C.

Do not refrigerate or freeze. Protect from frost.

Protect sachets from direct sunlight.

Shelf-life after first opening the immediate packaging:

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

Do not use after the expiry date stated on the border of the sachet.

12. SPECIAL WARNING(S)

Avoid contact with skin and eyes because of possible contact dermatitis and irritation. 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.

Higher dosage of the bee-hive strips than recommended can lead to impetuous behaviour of the colony and abundant dead bee and larvae (> 20) might be found in front of the hive entrance. To normalise the behaviour of the colony you should remove excess bee-hive strips of the hive.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{MM/YYYY} or <month YYYY>

15. OTHER INFORMATION

For animal treatment only.

Marketing authorisation number:

16. MARKETING AUTHORISATION NUMBER

Vm 36234/4000

Approved: 12 June 2019