SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

APIGUARD gel (25% thymol) for beehive use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A tray of 50 g of gel contains
Active substance
Thymol……..12.5 g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel.
Slightly opalescent, colourless to pink granular gel.

4. CLINICAL PARTICULARS

4.1 Target species

Honeybees (*Apis mellifera*).

4.2 Indications for use, specifying the target species

Treatment of varroosis due to *Varroa destructor.*

4.3 Contraindications

None known

4.4 **Special warnings** for each target species

Care should be taken to ensure that the authorised dosage schedule is adhered to as improper dosing could deleteriously affect the colony.
The product should be used as part of an integrated varroa control program.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not treat during honey flow to avoid potential taste tainting.
The treatment can be performed immediately after the removal of the supers.
Do not use the product when the maximum daily temperature expected during the treatment is lower than 15°C or when the colony activity is very low or when temperature is above 40°C.
Combine weak colonies before treatment.
All colonies of an apiary should be treated simultaneously.

ii) 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.
When handling the product, wear impermeable gloves as well as the usual protection equipment.
After application, wash hands and the material being in contact with the gel with soap and water.
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.
Do not inhale.

iii) Other precautions

4.6 Adverse reactions (frequency and seriousness)

A slight agitation of the colony during the treatment is possible.
Occasionally at high temperature some slight reduction in young brood can occur during the treatment period; this is transient and has no effect on the development of the colony.
Localised bee brood removal can sometimes occur in treated colonies. Normal bee behaviour involves removing or cleaning the gel from the tray above the brood frames with no effect on the colony; however, especially with more hygienic strains, some bees may occasionally remove uncapped bee brood from the vicinity of the product also. If this is observed, remove the product from the colony.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Treatment in the hive : two applications of 50 g of gel per colony at a 2 week interval.
Maximum of two treatments per year.

Method of administration

Open the hive. Peel back the foil lid of the tray leaving one corner of the lid attached to the tray. Place the open tray centrally on the top of the frames, gel side up. Ensure that there is a free space of at least 0.5 cm between the top of the tray and the hive cover board. Close the hive. After two weeks replace the first tray with a new one according to the same instruction. Leave the product in the colony until the tray is empty. Remove the product when installing the supers on the colony.

The efficacy of the product is maximised if the product is used in late summer after the honey harvest (when the amount of bee brood present is diminishing). However, in the case of severe infestations, the product can also be used during springtime, when temperatures are above 15°C.

Efficacy may vary between colonies due to the nature of the application. Therefore, the product should be used as one treatment among others within an Integrated Pest Management programme, and mitefall regularly monitored. If further significant mite fall is observed during the following Winter or Spring, it is recommended to use an additional secondary Winter or Spring treatment for varroa.

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

The use of a dose higher than the recommended (50 g gel per application corresponding to 12.5 g of thymol) could cause disturbances in the behaviour of the colony (agitation, absconding, or increased mortality). In case of overdose, remove the excess product from the colony.

4.11 Withdrawal period(s)

Honey: zero days.
Do not use during honey flow.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides for topical use, including insecticides
ATC Vet Code : QP53AX22

5.1 Pharmacodynamic properties

Thymol has acaricidal action. However, its exact mode of action is not fully understood. It acts directly on the mites through inhalation and contact. Protein denaturisation is one of the probable modes of action in mites.

5.2 Pharmacokinetic particulars

It is thought that 2/3 of the action is elicited by inhalation and 1/3 by direct contact through honeybees. However, the relative proportion of each route may vary with temperature and honeybee activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Triethanolamine
Water, purified

6.2 Major Incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 30°C.
Do not freeze.
Keep unopened in the original packaging.
Protect from direct sunlight.
Do not store the product near pesticides or other chemical substances which could contaminate the product.
Store away from foodstuffs.

6.5 Nature and composition of immediate packaging

Nature of the immediate packaging:
*Aluminium tray.
*Aluminium lid.

Model (s) for sale:
*Box of 10 trays of 50 g of gel.

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.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Vita (Europe) Ltd
Vita House
London Street
Basingstoke
Hampshire
RG21 7PG

8. MARKETING AUTHORISATION NUMBER

Vm 17017/4002

9. DATE OF FIRST AUTORISATION

23 July 2003

10. DATE OF REVISION OF THE TEXT

July 2018

Approved: 30 July 2018