

LABELLING AND PACKAGE LEAFLET

A. IMMEDIATE LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. Name of the veterinary medicinal product

APIGUARD gel (25% thymol) for beehive use

2. Quantity of the active substance

Thymol 12.5 g

3. Content by weight, by volume or by number of doses

50g of gel

4. Route of administration

In hive use

5. Withdrawal period

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

6. Batch number

BN

7. Expiry date

EXP

8. The words “for animal treatment only”

For animal treatment only.

LABELLING ON THE OUTER PACKAGE (WITHOUT PACKAGE INSERT)

APIGUARD gel (25% thymol) for beehive

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder

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

Manufacturer responsible for the batch release

Cicieffe s.r.l.
via. G. Marconi n. 13
24040 Fornovo San Giovanni (BG)
Italy

2. Name of the veterinary medicinal product

APIGUARD gel (25% thymol) for beehive use

3. Statement of active and other substances

Thymol 12.5 g/tray
Slightly opalescent, colourless to pink granular gel.

4. Indication

Treatment of varroosis due to *Varroa destructor*

5. Contraindications

None known.

6. Adverse reactions

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 Apiguard tray also. If this is observed, remove the product from the colony.

7. Target species

Honeybees (*Apis mellifera*).

8. Dosage for each species, route and method of administration

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.

9. Advice on correct administration

The treatment can be performed immediately after the removal of the supers. Combine weak colonies before treatment. All colonies of an apiary should be treated simultaneously

10. Withdrawal period

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

11. Special storage precautions

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.

12. Special warnings

Care should be taken to ensure that the authorised dosage schedule is adhered to as improper dosing could deleteriously affect the colony.

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

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.

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.

User precautions

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.

13. Special precautions for the disposal of unused product or waste materials

Any unused product or waste material should be disposed of in accordance with local requirements.

14. Date on which the package leaflet was last approved

March 2020

15. Package size

10 trays of 50g of gel

16. Expiry date

EXP

17. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children

18. Marketing authorisation number

Vm 17017/4002

19. Batch number

BN

20 THE WORDS “FOR ANIMAL TREATMENT ONLY”

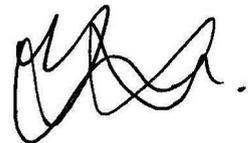
For animal treatment only. [all MS except PL]

For animal treatment only - subject to medical prescription.

Administration by a veterinary surgeon or under their direct responsibility. [PL]

B. PACKAGE LEAFLET

NONE

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 12 March 2020