[Version 8.2,01/2021]

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

APIGUARD MULTIDOSE 0.25 g/g bee-hive gel [ES, FR, IE, IT, PL]

APIGUARD Vet 12.5 g/dose bee-hive gel [SE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active substance
Thymol……..0.25g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bee-hive 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

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.

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.

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 (12.5 g thymol/dose) per colony at a 2-week interval.

Maximum of two treatments per year.

Method of administration
Open the hive. Place the dosing card (supplied) in the middle above the brood frames. The product should be mixed well before use with a hive tool or similar for 10 seconds. Using the dosing syringe (supplied), transfer the first dose of 50 g of gel from the container to the dosing card as follows:

Remove the dosing syringe from its sealed package. Push the syringe nozzle all the way into the gel, making sure that no air enters the syringe. Slowly pull back on the plunger to aspirate 52 ml (equivalent to 50 g) of gel. Pull the syringe out of the gel. Gently push the plunger to release the gel from the syringe progressively to the entire surface of the dosing card. .

Make sure that there is a free space of at least 0.5 cm between the top of the gel and the lid of the hive. Close the hive.

After completion of administration of the treatment to beehives, wash the syringe in warm water. Pull out the plunger completely and wash the apparatus thoroughly to remove traces of gel. Allow to dry and store in a sealed container until next use.

After 2 weeks replace the first dosing card with a new one and apply the second dose of 52ml (equivalent to 50g) gel following the same procedure.

Leave the product in the colony for a further 2 weeks until it totally disappears from the dosing card.
Remove the product when installing the supers on the colony.
Please see the pictograms below:

The efficacy of Apiguard Multidose 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, this product can also be used during springtime, when temperatures are above 15ºC.

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 Varroa control program, and mite fall 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.
Shelf life after first opening the immediate packaging: 3 years (and before the expiry date).

6.4. Special precautions for storage

Do not store above 30°C.
Do not freeze.
Keep the container tightly closed.
Protect from direct sunlight.
Do not store the product near pesticides or other chemical substances which could contaminate the product.
Store away from foodstuffs.
The remaining dosing cards should be kept in a dry and clean place.
Always load the cards with gel in a well ventilated area.
Keep the remaining dosing cards in the outer cardboard box

6.5 Nature and composition of immediate packaging

Cardboard box containing 2 containers of 3000g, 2 syringes and 4 sealed packs of 30 dosing cards.
Single 3000g container, 1 syringe and 2 sealed packs of 30 dosing cards
3000g Polypropylene container with a polypropylene lid.
Polypropylene Syringe
Polyethylene/Paper/Polyethylene dosing card

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

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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 [PL]