SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formicpro 68.2g Beehive Strips for Honey Bees

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Beehive Strip contains:

Active Substance:
Formic Acid: 68.2g

Excipients:
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Beehive strip.
Brown, semi-rigid to soft gel strip covered in a biodegradable laminated paper, which maintains form.

4. CLINICAL PARTICULARS

4.1 Target species

Honey bees

4.2 Indications for use, specifying the target species

Treatment of Varroosis caused by *Varroa destructor* in honey bees (*Apis mellifera*).

4.3 Contraindications

Do not use when daytime temperatures are outside the range of 10 – 29.5°C on the day of application. See sections 4.4 and 4.5.

Do not use for treatment of colonies less than 10,000 bees. A smaller colony might not be able to provide sufficient air flow to achieve a tolerable formic acid concentration.

4.4 Special warnings for each target species

The product should only be used as part of an integrated varroa control programme. It is highly recommended to monitor mite levels monthly during periods of brood rearing and treat when local thresholds are reached. Use according to local treatment recommendations, if available.

Take care to disturb the colony as little as possible during the application process.

Treat all colonies in the apiary at the same time, to avoid re-infestation from untreated colonies

Screen bottom boards should be closed off during treatment to optimize efficacy.

The safety and efficacy of the product has not been fully tested in horizontal hives such as Layens hives. Use only according to a thorough benefit/risk assessment and after consideration of possible integrated pest management alternatives.

4.5 Special precautions for use

Special precautions for use in animals

Do not disturb the colony during the treatment period. If the colony is disturbed during the treatment period, there is an increased risk of brood and/or adult bee (including queen) mortality, and absconding may also occur.

Natural birth and death rate is 1,000 to 2,000 bees per day during spring and summer, the natural death rate increases in the autumn as the large summer bee population is replaced by the smaller winter bee population. Under the stress of treatment, bees that are fragile due to age or maladies, (ones that normally would die away from the hive), may succumb within the hive, and can be observed around the entrance.

Temperatures: Outside daytime temperature highs should be in the temperature range given in section 4.3. Temperatures above this range during the first three days of treatment may cause increased brood mortality and a higher risk of queen loss, particularly in fragile queens. If such temperatures coincide with a dearth period (where food is in short supply), there is an elevated risk of queen loss, sudden supercedure, or delay in egg laying. Treatment should be postponed until temperatures drop or nectar flow resumes.

To avoid an intolerable formic acid concentration, it is essential to ensure sufficient ventilation during the treatment period. An entrance must be provided that is the full width of the hive (typically the bottom board entrance), with a minimum height 12.5 mm. Any restriction on air movement through the entrance

into the brood chamber (e.g. reducer or mouse guard) must be removed to prevent excessive damage to the colonies.
In hives with permanently reduced bottom entrances take appropriate measures to provide a sufficient level of ventilation (i.e. provision of alternative brood chamber entrances to act as ventilation slots). Refer to section 4.9 for further information.

Colonies should have good food reserves at time of treatment and should not be fed in-hive during treatment.

Do not destroy queen cells that may be observed prior to or post treatment. Supercedure, even if thought to be set in motion by treatment, is a natural process, and should be allowed to proceed for the health of the colony. Verify the colony is queen-right one month after treatment. Mother and daughter queens present post treatment are not uncommon.

In case of expanding colonies which require extra space, supers empty of honey may be placed on the hive at time of application.

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

- This veterinary medicinal product is irritating to the skin and eyes. Avoid contact with the skin, eyes and mucous membranes. When handling and applying the product, wear the usual beekeeping protective clothing. Have water readily available.
- In case of accidental eye contact, flush the eye(s) immediately with clear running water for 10 minutes, seek medical advice and show the package leaflet to the physician.
- Avoid contact with skin by wearing chemical resistant gloves (EN 374). In case of accidental skin contact, wash the exposed skin immediately with water and seek medical advice if irritation persists.
- Avoid inhalation of vapour. Only open the product container and unwrap strips outdoors, standing upwind of the product. In case of accidental inhalation move to fresh air and seek medical advice if irritation persists.
- If you cannot avoid working in a confined space, wear an appropriate half-mask or full-mask respirator with filters conforming to Type B or E.
- Keep children well away during application of product.
- Do not eat, drink or smoke whilst handling and applying the product.
- Always wash hands with soap and water directly after use.
- People with known sensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.

Other precautions
This product is corrosive. Do not allow product to contact metal surfaces.

4.6 Adverse reactions (frequency and seriousness)

Insufficient ventilation, high ambient temperatures and insufficient hive volume have been identified as particular risk factors for build-up of formic acid concentrations beyond easily tolerated levels. Specific requirements of section 4.3 and 4.5 should be carefully observed as there is an increased risk of adverse events if these are not followed.

In uncommon cases, increased adult bee mortality, brood mortality and/or queen loss have been observed, more so in smaller cavity hive designs or where entrance reducers were not removed prior to use. Secondary signs including bees absconding, reduced reproduction and/or total colony loss have been noted in consequence.

Moribund bees (e.g. those suffering from a viral infection or a high mite infestation) are more susceptible to toxic effects.

Formic acid will initially disturb colony activities and may, within one day of application, result in queen rejection, triggering queen supercedure activities in rare cases.

Colonies are expected to expand the cluster as part of controlling vapour concentration during the first 3 days of treatment. Bearding behaviour may be observed in very rare cases.

The frequency of adverse reactions is defined using the following convention.

- *very common (more than 1 in 10 colonies treated displaying adverse reaction(s))*
- *common (more than 1 but less than 10 colonies in 100 colonies treated)*
- *uncommon (more than 1 but less than 10 colonies in 1,000 colonies treated)*
- *rare (more than 1 but less than 10 colonies in 10,000 colonies treated)*
- *very rare (less than 1 colony in 10,000 colonies treated, including isolated reports.)'*

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medical products and other forms of interaction

Do not use with other acaricides against varroosis.

4.9 Amounts to be administered and administration route

VERTICALLY MODULAR HIVE TYPES (EXAMPLES: DADANT, LANGSTROTH)

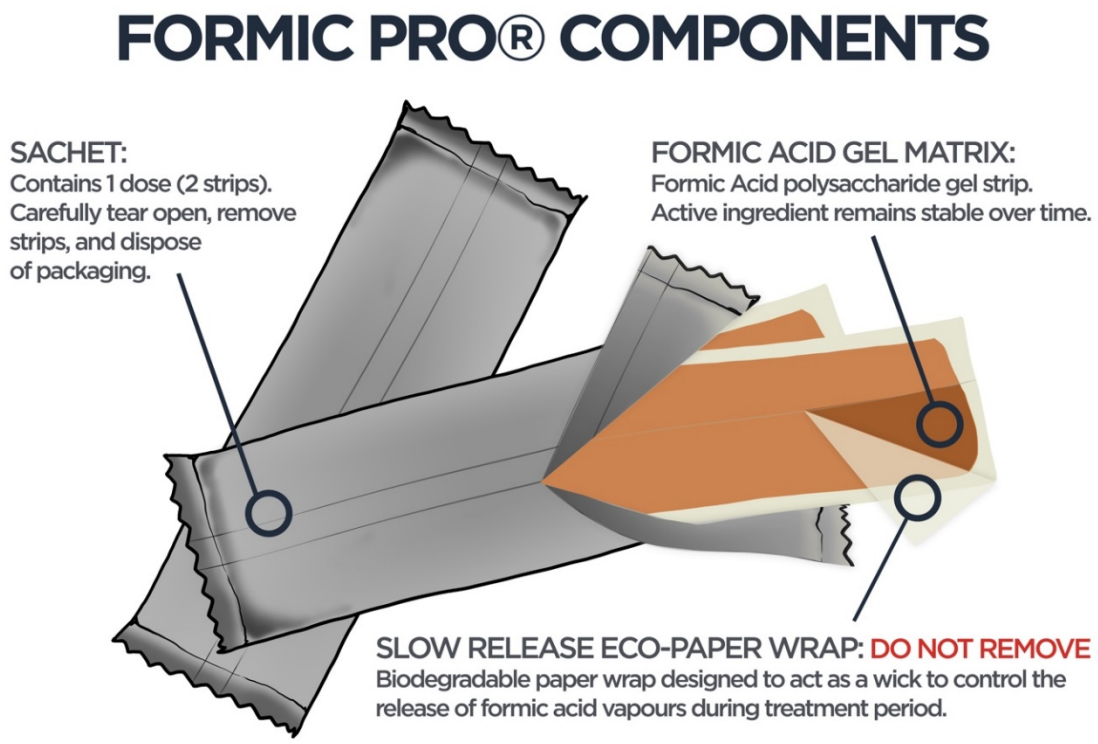
Dosage: 1 sachet (i.e. 2 strips) per hive for 7 days.
Allow a minimum of one month between applications.

GENERAL INSTRUCTIONS

Screen bottom boards should be closed off during treatment to optimize efficacy.

Once the hive is prepared, carefully remove the strips from the sachet and separate the two strips. **DO NOT REMOVE THE ECO-PAPER WRAP.** This acts as a wick (i.e. it controls the rate of the release of the active substance).

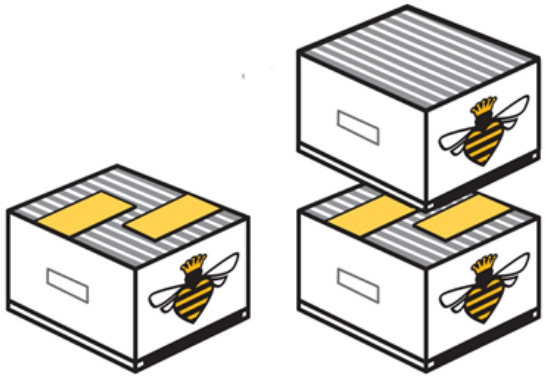
Do not disturb brood chamber frames during the application process. Place treatment on the top bars of the frames of the lower brood chamber. No additional spacer should be used; hive components must fit tightly together as the hive is reassembled.



DOSING INSTRUCTIONS

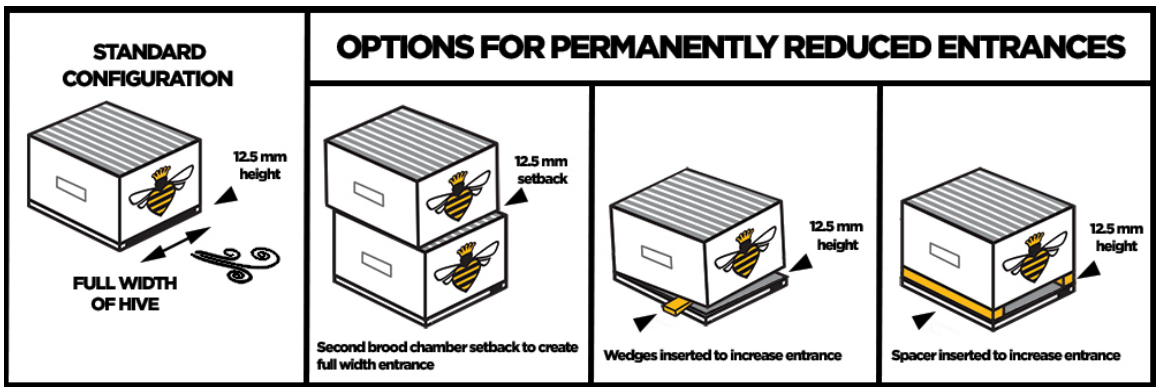
For double brood chamber hives; lay two strips, staggering them so they lay flat and across the full width of the lower brood chamber, in the heart of the brood rearing zone, with approximately 5 cm between strips and 10 cm between the ends of the brood chamber and the outer edges of the strips. For single brood

chamber hives lay two strips flat across the frames directly above the brood rearing zone with spacing as indicated above.



The bottom hive entrance needs to be open the full width of the hive, minimum 12.5 mm high, for the entire duration of the treatment, with no barriers into the brood chamber.

In hives with permanently reduced entrances take appropriate measures to provide equivalent ventilation slots. Examples are provided in the pictogram.



Spent strips do not need to be immediately removed at the end of the treatment period but must be removed before supers are placed back on the hive.

When removed, dispose of by composting.

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

Excessive mortality of adult bees and brood as well as absconding are typical overdose symptoms. These signs can be caused by exceeding the recommended dose, insufficient ventilation, high temperatures and/or inappropriate hive volume. In case of overdose, increase hive ventilation by creating additional entrances from top to bottom. Check for presence of the queen 2 weeks after application. See also sections 4.5 and 4.9.

4.11 Withdrawal period(s)

Honey: Zero days.

Supers with honey must be removed from the hive prior to product application. See Section 4.5. Honey stored in super(s) put on for the treatment period must be removed and not used for human consumption. Spent strips must be removed before supers intended for harvest are placed on the hive.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents, organic acids, formic acid

ATCvet code: QP53AG01

5.1 Pharmacodynamic properties

Formic acid from the product acts by fumigation, or vapour action.

Formic acid is active against mites on adult bees and is known to kill mite nymphs within capped brood cells. In addition, variable activity against male and female adult mites under the brood cap has been shown which may have consequences for mite reproduction since mating and fertilisation take place within cells.

The mode of action of formic acid has not been fully elucidated. The available data suggest that impairment of *Varroa destructor* may result from local effects that are due to the corrosive action of formic acid vapours. In addition, absorbed formic acid may cause acidosis and may impair the mite's energy supply through inhibition of the mitochondrial respiratory chain.

5.2 Pharmacokinetic particulars

The pharmacokinetics of formic acid in honeybees has not been studied.

Distribution and elimination in the beehive:

The formic acid volatilises slowly from the strips into the hive cavity. The honeybees determine the concentration of formic acid in the hive air by ventilating the brood area to their comfort level. Excess levels of formic acid vapours in the hive air are quickly replaced by fresh incoming air.

Peak in-hive concentrations of formic acid are achieved quickly after application of the strips. Typically, they are in the range of 55 - 85 µg/cm3 (ppm) following

the application of two strips, depending on hive configuration and colony response to weather conditions. Levels usually remain above 20 µg/cm3 (ppm) for several days.

Formic acid is naturally occurring in honey. Formic acid is not lipophilic, therefore it does not leave residues in the honeycomb.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn Starch
Liquid Sugar
Wood Flour
Laminated paper containing biodegradable polymers
Xanthan Gum
Potable Water

6.2 Major Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Store in the original container.
Protect from direct sunlight.
Store indoors in a cool, dry and well-ventilated place.

An alteration in colour from light brown to dark brown may be observed during storage due to the potential for caramelisation of the gel matrix.

6.5 Nature and composition of immediate packaging

A polypropylene/aluminium foil/polypropylene laminated sachet containing two strips.

Pack size:
Cardboard box containing a plastic liner (with resealable tape) with 2 sachets (4 strips)
Cardboard box containing a plastic liner (with resealable tape) with 10 sachets (20 strips)
Cardboard box containing a plastic liner (with resealable tape) with 30 sachets

(60 strips)
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Limited
Tullow Industrial Estate
Tullow
Co Carlow
Ireland
R93 W0D8

8. MARKETING AUTHORISATION NUMBER

Vm 50769/4001

9. DATE OF FIRST AUTHORISATION

12 May 2021

10. DATE OF REVISION OF THE TEXT

June 2022

Approved 15 June 2022