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 'Advice on correct administration' 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.	
IF IN EYES	• 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.
IF ON SKIN OR CLOTHING	• 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.
IF INHALED	• 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.

Interaction with other medicinal products and other forms of interaction:
Do not use with other acaricides against varroosis.

Overdose (symptoms, emergency procedures, antidotes):
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 section 'Special precautions for use in animals' and 'Advice on correct administration'.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via household waste. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

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.

UK
Vm 50769/4001 AVM-GSL

IE
VPA 22670/002/001 LM
Licensed Merchant

UK-IE-FP-PL-001

FORMICPRO

68.2G BEEHIVE STRIPS FOR HONEY BEES
FORMIC ACID

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

Marketing authorisation holder:	Manufacturer responsible for batch release:
NOD Apiary Ireland Ltd. 5 George's Dock IFSC Dublin 1 D01 X8N7 Ireland	Lohmann Pharma Herstellung GmbH Heinz-Lohmann-Strasse 5 27472 Cuxhaven Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formicpro 68.2g Beehive Strips for Honey Bees
Formic Acid

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each Beehive Strip contains:
Active Substance:
Formic Acid: 68.2g

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use when daytime temperatures are outside the range of 10 – 29.5°C on the day of application. See 'Special Warnings' also.

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.

6. ADVERSE REACTIONS

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 the contraindications and special warnings sections 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.)*

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system www.gov.uk/report-veterinary-medicine-problem or www.hpra.ie.

7. TARGET SPECIES
Honey bees

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Dosage: 1 sachet (i.e. 2 strips) per hive for 7 days. Allow a minimum of one month between applications.

9. ADVICE ON CORRECT ADMINISTRATION
VERTICALLY MODULAR HIVE TYPES (EXAMPLES: DADANT, LANGSTROTH)

GENERAL INSTRUCTIONS

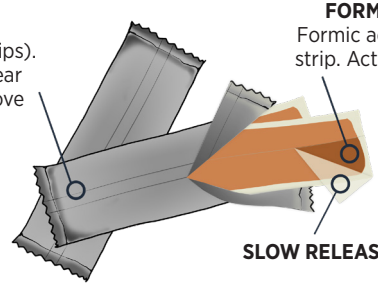
Screen bottom boards should be closed off during treatment to optimize efficacy.

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.

FORMICPRO® Components

SACHET:
Contains 1 dose (2 strips). Carefully tear open, remove strips, and dispose of packaging.

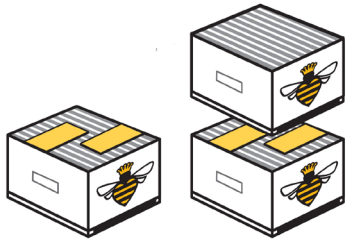


FORMIC ACID GEL MATRIX:
Formic acid polysaccharide gel strip. Active ingredient remains stable over time.

SLOW RELEASE ECO-PAPER WRAP:
DO NOT REMOVE
Biodegradable paper wrap designed to act as a wick to control the release of the formic acid vapours during treatment period.

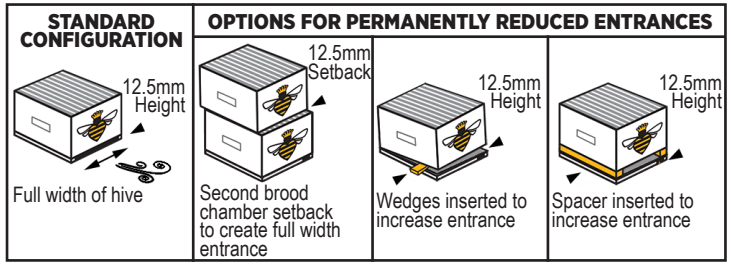
DOSING INSTRUCTIONS

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.

10. WITHDRAWAL PERIOD(S)
Honey: Zero days.
Supers with honey must be removed from the hive prior to product application. See Section 'Special precautions for use in animals'. 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.

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.

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.

12. SPECIAL WARNING(S)
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.

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 'Contraindications' 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