1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formicpro 68.2 g Beehive Strips for Honey Bees (AT, BE, BG, HR, CZ, FR, DE, EL, HU, IT, IE, LT, NL, PT, RO, SK, SI, ES, UK)

Formicprotect 68.2 g Beehive Strip for Honey Bees (PL)

MAQSplus vet 68.2 g Beehive Strip for Honey Bees (DK, NO)

Formic acid NOD 68.2 g Beehive Strip for Honey Bees (SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each beehive strip contains:

Active substances:
Formic Acid: 68.2g

Excipients:

Qualitative composition of excipients and other constituents
Corn starch
Liquid sugar
Wood flour
Laminated paper containing biodegradable polymers
Xanthan gum
Potable water

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

3. CLINICAL INFORMATION

3.1 Target species

Honey bees.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use when daytime temperatures are outside the range of 10 – 29.5 °C on the day of application. See sections 3.4 and 3.5.

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.

3.4 Special warnings

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 optimise 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 3.3. 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 3.9 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. Avoid inhalation of vapour.

People with known hypersensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.

Personal protective equipment consisting of the usual beekeeping protective clothing and chemical resistant gloves (EN 374) should be worn when handling the veterinary medicinal product.
Have water readily available.

Only open the product container and unwrap strips outdoors, standing upwind of the product.
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 should be worn when handling the veterinary medicinal product.

In case of accidental eye contact, flush the eye(s) immediately with clear running water for 10 minutes, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of direct contact with skin, wash the exposed skin immediately with water and if irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of accidental inhalation move to fresh air and if irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

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

3.6 Adverse events

Honey bees:

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 3.3 and 3.5 should be carefully observed as there is an increased risk of adverse events if these are not followed.

Uncommon (1 to 10 animals / 1 000 animals treated):	Increased mortality rate[1], bee brood mortality[1], queen bee loss[1] Bees absconding[2], bee colony death[2], loss of egg-quantity[2]
Rare (1 to 10 animals / 10 000 animals treated):	Queen bee rejection[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Behavioural disorders[4]

[1] Increased frequence may be observed in smaller cavity hive designs or where entrance reducers were not removed prior to use.
[2] Secondary signs to increased mortality rate, bee brood mortality, queen bee loss
[3] Formic acid will initially disturb colony activities and may, within one day of application, triggering queen supercedure activities.
[4] Bearding behaviour. Colonies are expected to expand the cluster as part of controlling vapour concentration during the first 3 days of treatment.

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use with other acaricides against varroosis.

3.9 Administration routes and dosage

In-hive use.

In vertically modular hive types (examples: Dadant, Langstroth).

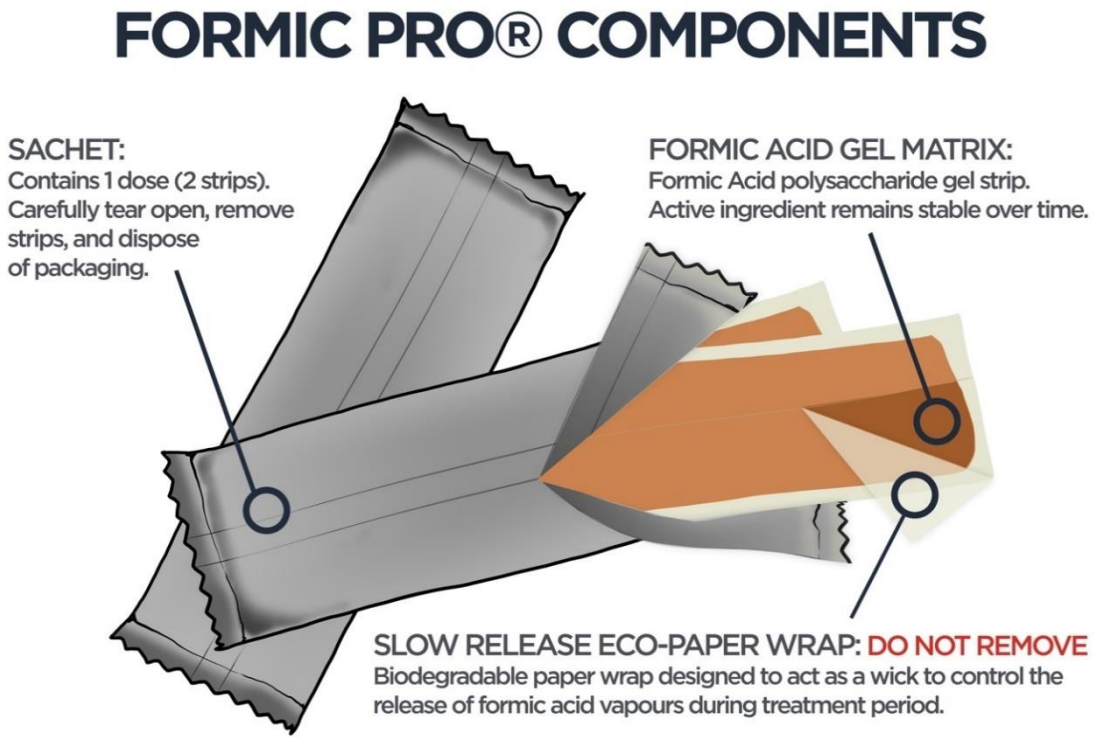
Dosage: 1 sachet (i.e. 2 strips) per hive for 7 days.
Allow a minimum of one month between applications.

GENERAL INSTRUCTIONS

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

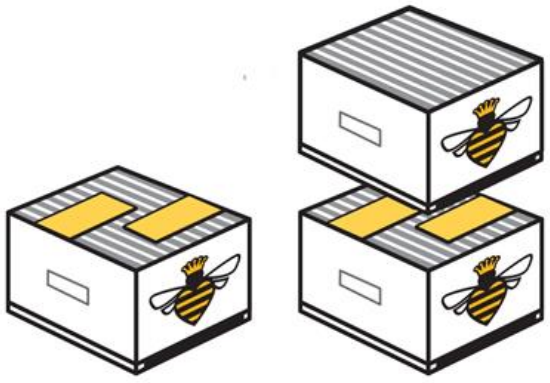
Once the hive is prepared, carefully remove the strips from the sachet and separate the two strips. **DO NOT REMOVE THE ECO-PAPER WRAP.** This acts as a wick (i.e. it controls the rate of the release of the active substance).

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.



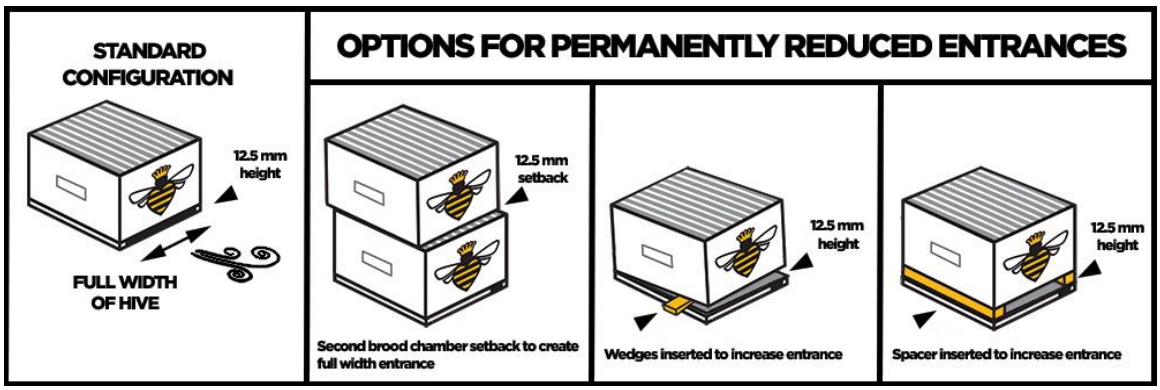
DOSING INSTRUCTIONS

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 sections 3.5 and 3.9.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Honey: Zero days.

Supers with honey must be removed from the hive prior to product application. See Section 3.5. 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP53AG01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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/cm^3 (ppm) following the application of two strips, depending on hive configuration and colony response to weather conditions. Levels usually remain above 20 µg/cm^3 (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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Store in the original package
Protect from direct sunlight.
Store in a 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.

5.4 Nature and composition of immediate packaging

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

Pack sizes:
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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or <household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. [BG, EL, ES, HU, PL, RO]
Veterinary medicinal product not subject to prescription. [AT, BE, CZ, DE, DK, FR, HR, IE, IT, LT, NL, NO, PT, SE, SI, SK, UK-NI]

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formicpro 68.2 g Beehive Strips (AT, BE, BG, HR, CZ, FR, DE, EL, HU, IT, IE, LT, NL, PT, RO, SK, SI, ES, UK)

Formicprotect 68.2 g Beehive Strip (PL)

MAQSplus vet 68.2 g Beehive Strip (DK, NO)

Formic acid NOD 68.2 g Beehive Strip (SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each beehive strip contains:

Active substances:

Formic Acid	68.2g

3. PACKAGE SIZE

2 sachets (4 strips)
10 sachets (20 strips)
30 sachets (60 strips)

4. TARGET SPECIES

Honey bees

5. INDICATIONS

For products not subject to veterinary prescription

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

6. ROUTES OF ADMINISTRATION

In-hive use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Honey: Zero days.
Supers with honey must be removed from the hive prior to product application. 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Protect from direct sunlight.
Store in a 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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Limited

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Formicpro 68.2 g Beehive Strips(AT, BE, BG, HR, CZ, FR, DE, EL, HU, IT, IE, LT, NL, PT, RO, SK, SI, ES, UK)

Formicprotect 68.2 g Beehive Strip(PL)

MAQSplus vet 68.2 g Beehive Strip(DK, NO)

Formic acid NOD 68.2 g Beehive Strip(SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each beehive strip contains:

Active substances:

Formic Acid 68.2g

3. TARGET SPECIES

Honey bees

4. ROUTES OF ADMINISTRATION

In-hive use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Honey: Zero days.
Supers with honey must be removed from the hive prior to product application. 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.

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Protect from direct sunlight.
Store in a 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

NOD Apiary Ireland Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Formicpro 68.2 g Beehive Strips for Honey Bees (AT, BE, BG, HR, CZ, FR, DE, EL, HU, IT, IE, LT, NL, PT, RO, SK, SI, ES, UK)

Formicprotect 68.2 g Beehive Strip for Honey Bees (PL)

MAQSplus vet 68.2 g Beehive Strip for Honey Bees (DK, NO)

Formic acid NOD 68.2 g Beehive Strip for Honey Bees (SE)

2. Composition

Each beehive strip contains:

Active substances:
Formic Acid: 68.2g

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

3. Target species

Honey bees.

4. Indications for use

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. Special warnings

Special warnings:
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 optimise 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 safe use in the target species:

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 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. Avoid inhalation of vapour.

People with known hypersensitivity to formic acid or oxalic acid should administer the veterinary medicinal product with caution.

Personal protective equipment consisting of the usual beekeeping protective clothing and chemical resistant gloves (EN 374) should be worn when handling the veterinary medicinal product.
Have water readily available.

Only open the product container and unwrap strips outdoors, standing upwind of the product.
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 when handling the veterinary medicinal product.

In case of accidental eye contact, flush the eye(s) immediately with clear running water for 10 minutes, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of direct contact with skin, wash the exposed skin immediately with water and if irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of accidental inhalation move to fresh air and if irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

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:
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 section ‘Special precautions for safe use in the target species’ and ‘Advice on correct administration’.

7. Adverse events

Honey bees:

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 sections 'Contraindications' and 'Special precautions for safe use in the target species' should be carefully observed as there is an increased risk of adverse events if these are not followed.

Uncommon (1 to 10 animals / 1 000 animals treated):	Increased mortality rate[1], bee brood mortality[1], queen bee loss[1] Bees absconding[2], bee colony death[2], loss of egg-quantity[2]
Rare (1 to 10 animals / 10 000 animals treated):	Queen bee rejection[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Behavioural disorders[4]

[1] Increased frequence may be observed in smaller cavity hive designs or where entrance reducers were not removed prior to use.
[2] Secondary signs to increased mortality rate, bee brood mortality, queen bee loss.
[3] Formic acid will initially disturb colony activities and may, within one day of application, triggering queen supercedure activities.
[4] Bearding behaviour. Colonies are expected to expand the cluster as part of controlling vapour concentration during the first 3 days of treatment.

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

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

In-hive use.

In 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.

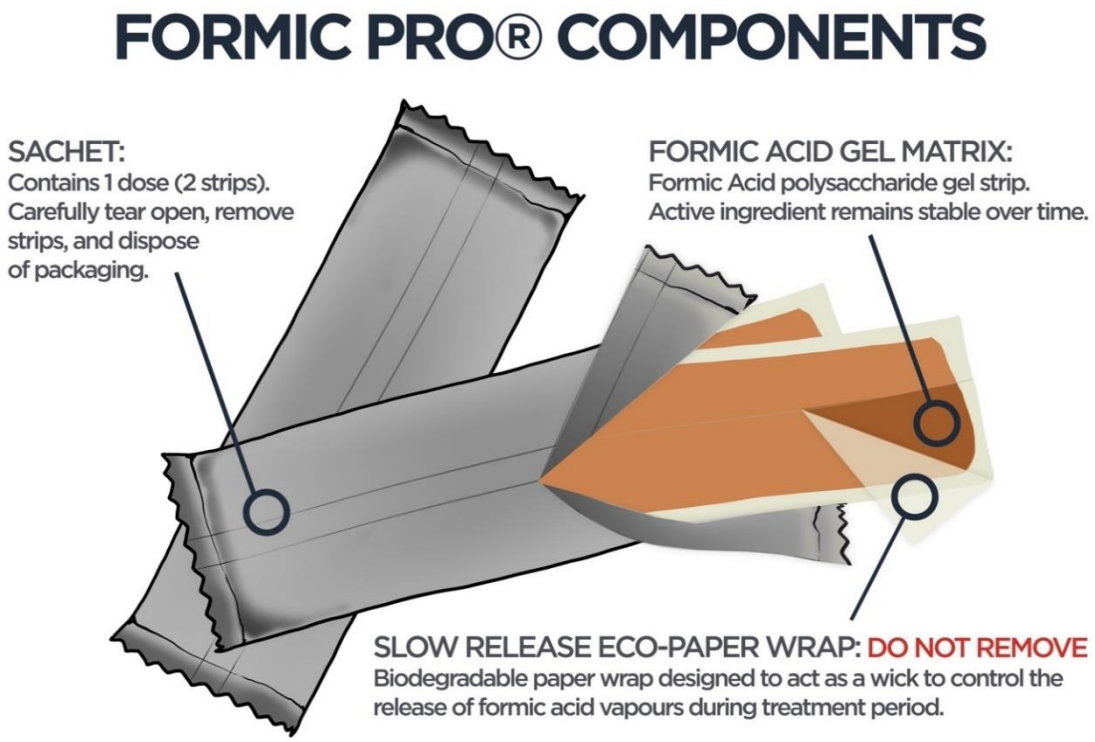
9. Advice on correct administration

GENERAL INSTRUCTIONS

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

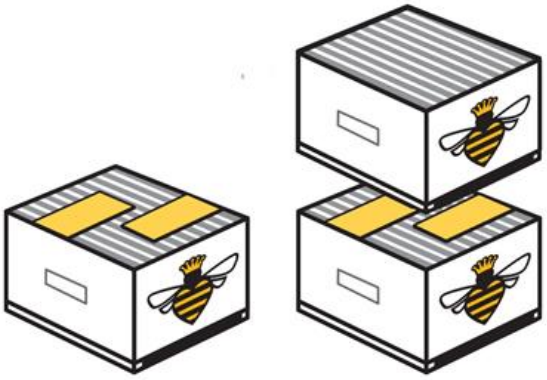
Once the hive is prepared, carefully remove the strips from the sachet and separate the two strips. **DO NOT REMOVE THE ECO-PAPER WRAP.** This acts as a wick (i.e. it controls the rate of the release of the active substance).

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.



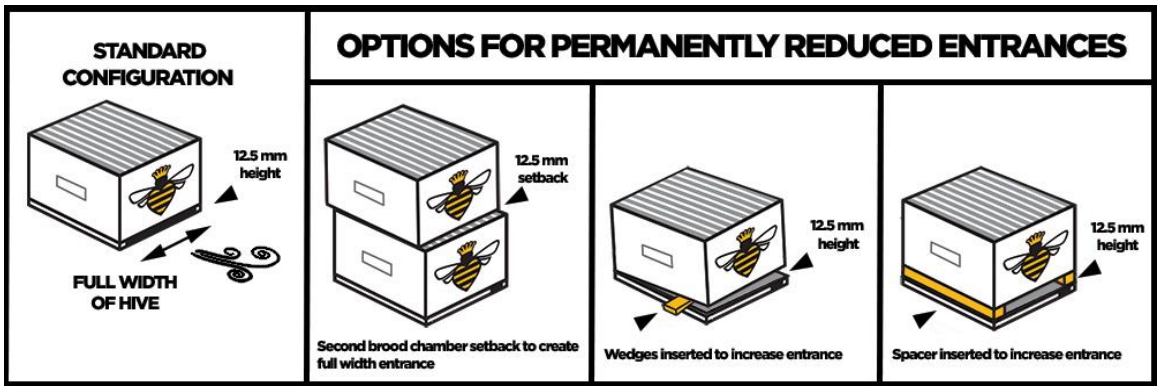
DOSING INSTRUCTIONS

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.

10. Withdrawal periods

Honey: Zero days.

Supers with honey must be removed from the hive prior to product application. See Section 'Special precautions for safe use in the target species'. 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 package.
Protect from direct sunlight.
Store in a 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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

<Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.>

13. Classification of veterinary medicinal products

<Veterinary medicinal product subject to prescription.>
<Veterinary medicinal product not subject to prescription.>

14. Marketing authorisation numbers and pack sizes

Pack sizes:
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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
NOD Apiary Ireland Limited
Clieveragh Industrial Estate
Listowel
Kerry
V31 FX29
Ireland
Tel: +353 6838006

Manufacturer responsible for batch release:
Animal Health Distributor (AHD)
Tullow Industrial Estate
Tullow
Co Carlow
R93 WOD8
Ireland

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information