

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**Cardboard box (PP/ALU foil and package leaflet included)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fiprotec 67 mg Spot On Solution for Small Dogs
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES**Active substance:**

Fipronil67.0 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 0.50 ml
2 x 0.50 ml
3 x 0.50 ml
4 x 0.50 ml
6 x 0.50 ml

5. TARGET SPECIES

Dogs

This product is suitable for dogs weighing 2 to 10 kg.

6. INDICATION(S)

The treatment and prevention of flea (*Ctenocephalides felis*) infestations in dogs. The duration of protection against flea infestations is 5 weeks.

The product protects against new tick (*Dermacentor reticulatus*, *Rhipicephalus sanguineus*) infestations in dogs from day 7 to day 28 after application of the product. The product has not been shown to be effective when ticks are already present.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How to apply Fiprotec:



Route of administration – By topical application to the skin.

Dosage:

- 1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight
The dosing rate is 6.7 – 33.5 mg fipronil per kg bodyweight.

Make sure you use the correct product, corresponding to the bodyweight of your dog.

For external use only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

n.a.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Use immediately after first opening the blister.

Do not store above 25°C.

Keep pipette within blister and box until ready for use, in order to protect from light.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.
Drostenkamp 3
8101 BX, Raalte
The Netherlands
T: +31 572 348 834
F: +31 572 348 835
E: hqb@beaphar.com

16. MARKETING AUTHORISATION NUMBER

Vm 41941/4001

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**Cardboardbox (Barex® foil, no package leaflet included)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fiprotec 67 mg Spot On Solution for Small Dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 pipette of 0.67 ml contains:

Active substance:

Fipronil.....67.0 mg

Excipients:

Butylhydroxyanisole (E320)0.134 mg

Butylhydroxytoluene (E321).....0.067 mg

Benzyl alcohol (E1519)190.950 mg

Clear colourless to slightly yellow solution

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1x 0.67 ml

2x 0.67 ml

3x 0.67 ml

6x 0.67 ml

5. TARGET SPECIES

Dogs

This product is suitable for dogs weighing 2 to 10 kg.

6. INDICATION(S)

The treatment and prevention of flea (*Ctenocephalides felis*) infestations in dogs. The duration of protection against flea infestations is 5 weeks.

The product protects against new tick (*Dermacentor reticulatus*, *Rhipicephalus sanguineus*) infestations in dogs from day 7 to day 28 after application of the product. The product has not been shown to be effective when ticks are already present.

7. METHOD AND ROUTE(S) OF ADMINISTRATION



Route of administration – By topical application to the skin.

Dosage:

- 1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10kg bodyweight
The dosing rate is 6.7 – 33.5 mg fipronil per kg bodyweight.

Make sure you use the correct product, corresponding to the bodyweight of your dog.

For external use only.

Keep pipettes in the original packaging until required for use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Before every use, read the information on the inside of the box for full instructions and all warnings, including user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Use immediately after first opening.

Do not store above 25°C.

Keep pipette within blister until ready for use, in order to protect from light.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.
Drostenkamp 3
8101 BX, Raalte
The Netherlands
T: +31 572 348 834
F: +31 572 348 835
E: hqb@beaphar.com

16. MARKETING AUTHORISATION NUMBER

Vm 41941/4001

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE INSIDE OF THE Cardboard BOX**Cardboard box (Barex® foil, no package leaflet included)****1. CONTRAINDICATIONS**

Do not use on dogs less than 8 weeks old and/or weighing less than 2 kg.

Do not use in cases of allergy to the active substance or to any of the other ingredients.

Do not use on sick animals or animals recovering from illness.

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

2. ADVERSE REACTIONS

If licking occurs, a brief period of excessive drooling/salivation may be observed due mainly to the nature of the carrier.

Suspected adverse reactions such as transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported very rarely after use. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed very rarely after use. Do not overdose. The risk of adverse effects may increase in cases of over-dose. 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

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

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

3. ADVICE ON CORRECT ADMINISTRATION

Method of administration – Hold upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Cut off the top of the pipette with scissors.

Part the coat between the shoulder blades and at the base of the head until the skin is visible. Place the tip of the pipette on the skin and gently apply half of its contents onto the skin at both application sites.

Avoid applying the solution onto the fur and do not rub into the skin.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24-48 hours post-application.

In the absence of safety studies, do not apply more often than every four weeks.

4. SPECIAL WARNING(S), IF NECESSARY

Special warnings for each target species

For optimal control of flea infestation in multi-pet household, all animals in the household should be treated with a suitable insecticide.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

No data on the effect of bathing/shampooing on the efficacy in dogs are available. Shampooing prior to or frequently after treatment may reduce how well the product works.

The product does not prevent ticks from attaching to the animal. In addition, it is not known whether the product will work against existing tick infestations.. For this reason, transmission of infectious diseases from the tick to the pet cannot be excluded.

It is known that the product will protect against new tick infestation from day 7 to day 28 after application of the product. However, it is not known whether it will work against new tick infestations - beyond 4 weeks following application. Therefore, there may be gaps in protection against ticks after subsequent re-applications of the product, even if the product is re-applied at the minimum interval of 4 weeks.

Special precautions for use in animals

For external use only. Do not apply the product on wounds or damaged skin.

Avoid contact with the animal's eyes. In case of accidental eye contact immediately and thoroughly flush the eyes with water.

Animals should be weighed accurately prior to treatment.

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

The potential toxicity of the product for puppies less than 8 weeks of age in contact with a treated bitch is not documented. Use according to a benefit/risk assessment by the responsible veterinarian

Do not use simultaneously with other flea products which are applied directly onto the animal.

User warnings

Keep pipettes in original packaging until ready for use and dispose of used pipettes immediately.

Persons with known hypersensitivity (allergy) to fipronil or to any of the other ingredients should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

In case of accidental eye contact, rinse the eye carefully with plain water.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the doctor.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.

Do not smoke, drink or eat during application.

Wash hands after use.

Other precautions

Fipronil may adversely affect aquatic organisms.

Dogs should not be allowed to swim in watercourses for 2 days after application.

The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Use during pregnancy, lactation or lay

Do not use in pregnant dogs or where the dog is providing milk for puppies.

Laboratory studies using fipronil have not produced any evidence of teratogenic or fetotoxic effects. The safety of the product has not been established in pregnant or lactating bitches use only according to the benefit/risk assessment by the responsible veterinarian. If animals are treated during the lactating period see section 4.5 (i).

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

No adverse effects have been demonstrated in the tolerance studies carried out with puppies 8 weeks, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of causing side effects may however increase with overdosing. It is therefore recommended to always treat animals with the appropriate pipette size.

5. DATE ON WHICH THE LABELLING TEXT WAS LAST APPROVED
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6. OTHER INFORMATION

1, 2, 3, 6 pipettes are packed in a cardboard box.
Not all pack sizes may be marketed.

Manufacturer responsible for batch release:

Laboratorios Calier, S.A.
Barcelonès, 26 – Pla del Ramassà
08520 Les Franqueses del Vallès
(Barcelona)
SPAIN
Telf.: +34 93 849 51 33
Fax.: + 34 93 840 13 98
e-mail: laboratorios@calier.es

Beaphar B.V.
Oude Lindertseweg 9
8102 EV Raalte
Netherlands
Telephone +31 572 348 834
Telefax: +31 572 348 835
E-Mail: hqb@beaphar.com

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE
PACKAGING UNITS
Blister (ALU FOIL)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 67 mg spot-on solution for small dogs

(2-10 kg)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil67.0 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 0.67 ml

2 x 0.67ml

3 x 0.67 ml

4 x 0.67 ml

6 x 0.67 ml

4. ROUTE(S) OF ADMINISTRATION

Topical application to the skin

5. WITHDRAWAL PERIOD(S)

n.a.

6. BATCH NUMBER

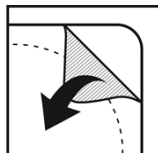
Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.



Extra information:

Beaphar B.V.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Pipette (PP foil)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 67 mg fipronil
optional



(2-10 kg) *(this symbol is*

2. NAME OF THE MARKETING AUTHORISATION HOLDER

See alu blister

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot{number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

See alu blister

MINIMUM PARTICULARS TO APPEAR ON PIPETTES AND BLISTERS

(Barex® foil)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 67 mg dog small spot-on
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.

3. EXPIRY DATE

{month/year}

4. BATCH NUMBER

{number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET
(Only included in case of PP/ALU foil)

PACKAGE LEAFLET:

Fiprotec 67 mg spot-on solution for small dogs

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

Marketing authorisation holder:

Beaphar B.V.
Drostenkamp 3
8101 BX, Raalte
The Netherlands
T: +31 572 348 834
F: +31 572 348 835
E: hqb@beaphar.com

Manufacturer responsible for batch release:

Laboratorios Calier, S.A.
Barcelonès, 26 – Pla del Ramassà
08520 Les Franqueses del Vallès
(Barcelona)
SPAIN
Telf.: +34 93 849 51 33
Fax.: + 34 93 840 13 98
e-mail: laboratorios@calier.es

Beaphar B.V.
Oude Lindertseweg 9
8102 EV Raalte
Netherlands
Telephone +31 572 348 834
Telefax: +31 572 348 835
E-Mail: hqb@beaphar.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 67 mg spot-on solution for small dogs
Fipronil



(2-10 kg)

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

1 pipette of 0.67 ml contains:

Active substance:

Fipronil.....67.0 mg

Excipients:

Butylhydroxyanisole (E320)0.134 mg
Butylhydroxytoluene (E321).....0.067 mg

Benzyl alcohol (E1519)190.950 mg

Clear colourless to slightly yellow solution

4. INDICATION(S)

The treatment and prevention of flea (*Ctenocephalides felis*) infestations in dogs. The duration of protection against flea infestations is 5 weeks.

The product protects against new tick (*Dermacentor reticulatus*, *Rhipicephalus sanguineus*) infestations in dogs from day 7 to day 28 after application of the product. The product has not been shown to be effective when ticks are already present.

5. CONTRAINDICATIONS

Do not use on dogs less than 8 weeks old and/or weighing less than 2 kg.

Do not use in cases of allergy to the active substance or to any of the other ingredients.

Do not use on sick animals or animals recovering from illness.

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

6. ADVERSE REACTIONS

If licking occurs, a brief period of excessive drooling/salivation may be observed due mainly to the nature of the carrier.

Suspected adverse reactions such as transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported very rarely after use. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed very rarely after use.

Do not overdose. The risk of adverse effects may increase in cases of overdose.

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.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

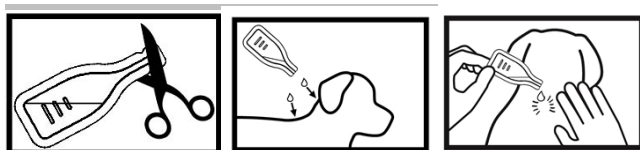
7. TARGET SPECIES

Dogs

This product is suitable for dogs weighing 2 to 10 kg.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

How to apply Fiprotec:



Route of administration – By topical application to the skin.

Dosage:

- 1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight

The dosing rate is 6.7 – 33.5 mg fipronil per kg bodyweight.

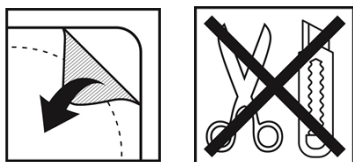
Make sure you use the correct product, corresponding to the bodyweight of your dog.

For external use only.

Keep pipettes in the original packaging until required for use.

9. ADVICE ON CORRECT ADMINISTRATION

Use the easy-peel corners to remove a pipette from its blister. Do not puncture the foil with scissors, knives or other sharp instruments, as this may damage the pipette inside.



Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Cut off the top of the pipette with scissors.

Part the coat between the shoulder blades and at the base of the head until the skin is visible. Place the tip of the pipette on the skin and gently apply half of its contents onto the skin at both application sites.

Avoid applying the solution onto the fur and do not rub into the skin. Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24-48 hours post application.

In the absence of safety studies, do not apply more often than every four weeks.

10. WITHDRAWAL PERIOD(S)

n.a.

11. SPECIAL STORAGE PRECAUTIONS

Use immediately after first opening the blister.

Do not store above 25°C.

Keep pipette within blister and box until ready for use, in order to protect from light.

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species

For optimal control of flea infestations in multi-pet households, all animals in the household should be treated with a suitable insecticide.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

No data on the effect of bathing/shampooing on the efficacy in dogs are available. Shampooing prior to or frequently after treatment may reduce how well the product works.

The product does not prevent ticks from attaching to the animal. In addition, it is not known whether the product will work against existing tick infestations. For this reason, transmission of infectious diseases from the tick to the pet cannot be excluded.

It is known that the product will protect against new tick infestations from day 7 to day 28 after application of the product. However, it is not known whether it will work against new tick infestations - beyond 4 weeks following application.

Therefore, there may be gaps in protection against ticks after subsequent re-applications of the product, even if the product is re-applied at the minimum interval of 4 weeks.

Special precautions for use in animals

For external use only. Do not apply the product on wounds or damaged skin. Avoid contact with the animal's eyes. In case of accidental eye contact immediately and thoroughly flush the eyes with water.

Animals should be weighed accurately prior to treatment.

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

The potential toxicity of the product for puppies less than 8 weeks of age in contact with a treated bitch is not documented. Use according to a benefit/risk assessment by the responsible veterinarian. Do not use simultaneously with other flea products which are applied directly onto the animal.

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

Keep pipettes in original packaging until ready for use and dispose of used pipettes immediately.

Persons with known hypersensitivity (allergy) to fipronil or to any of the other ingredients should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

In case of accidental eye contact, rinse the eye carefully with plain water.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. .

In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the doctor.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.

Do not smoke, drink or eat during application.

Wash hands after use.

Other precautions

Fipronil may adversely affect aquatic organisms.

Dogs should not be allowed to swim in watercourses for 2 days after application.

The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Use during pregnancy, lactation or lay

Do not use in pregnant dogs or where the dog is providing milk for puppies.

Laboratory studies using fipronil have not produced any evidence of teratogenic or fetotoxic effects. The safety of the product has not been established in pregnant or lactating bitches use only according to the benefit/risk assessment by the responsible veterinarian. If animals are treated during the lactating period see section 4.5 (i).

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

No adverse effects have been demonstrated in the tolerance studies carried out with 8-week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of causing side effects may however increase with overdosing. It is therefore recommended to always treat animals with the appropriate pipette size.

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

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

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**15. OTHER INFORMATION**

1, 2, 3, 4, 6 pipettes are packed in a cardboard box.

Not all pack sizes may be marketed.

Approved: 08 August 2019

