ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg
Chanhold 30 mg spot-on solution for dogs 2.6–5.0 kg
Chanhold 45 mg spot-on solution for cats 2.6–7.5 kg
Chanhold 60 mg spot-on solution for cats 7.6–10.0 kg
Chanhold 60 mg spot-on solution for dogs 5.1–10.0 kg
Chanhold 120 mg spot-on solution for dogs 10.1–20.0 kg
Chanhold 240 mg spot-on solution for dogs 20.1–40.0 kg
Chanhold 360 mg spot-on solution for dogs 40.1–60.0 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose (pipette) delivers:

Active substance:

Chanhold 15 mg for cats and dogs	6% w/v solution	Selamectin	15 mg
Chanhold 30 mg for dogs	12% w/v solution	Selamectin	30 mg
Chanhold 45 mg for cats	6% w/v solution	Selamectin	45 mg
Chanhold 60 mg for cats	6% w/v solution	Selamectin	60 mg
Chanhold 60 mg for dogs	12% w/v solution	Selamectin	60 mg
Chanhold 120 mg for dogs	12% w/v solution	Selamectin	120 mg
Chanhold 240 mg for dogs	12% w/v solution	Selamectin	240 mg
Chanhold 360 mg for dogs	12% w/v solution	Selamectin	360 mg

Excipients:

Butylated hydroxytoluene (E321) 0.08%.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear colourless to yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Cats and dogs:

- **Treatment and prevention of flea infestations** caused by *Ctenocephalides* spp. for one month following a single administration. This is as a result of the adulticidal, larvicidal and ovicidal properties of the product. The product is ovicidal for 3 weeks after

administration. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will also aid in the prevention of flea infestations in the litter up to seven weeks of age. The product can be used as part of a treatment strategy for flea allergy dermatitis and through its ovicidal and larvicidal action may aid in the control of existing environmental flea infestations in areas to which the animal has access.

- **Prevention of heartworm disease** caused by *Dirofilaria immitis* with monthly administration.

The product may be safely administered to animals infected with adult heartworms, however, it is recommended, in accordance with good veterinary practice, that all animals 6 months of age or more living in countries where a vector exists should be tested for existing adult heartworm infections before beginning medication with the product. It is also recommended that dogs should be tested periodically for adult heartworm infections, as an integral part of a heartworm prevention strategy, even when the product has been administered monthly. This product is not effective against adult *D. immitis.*

- **Treatment of ear mites** (*Otodectes cynotis*).

Cats:
- Treatment of biting lice infestations *(Felicola subrostratus*)
- Treatment of adult roundworms (*Toxocara cati*)
- Treatment of adult intestinal hookworms (*Ancylostoma tubaeforme).*

Dogs:
- Treatment of biting lice infestations (*Trichodectes canis*)
- Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*)
- Treatment of adult intestinal roundworms (*Toxocara canis*).

4.3 Contraindications

Do not use in animals under 6 weeks of age.
Do not use in cats that are suffering from concomitant disease, or are debilitated and underweight (for size and age).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Animals may be bathed 2 hours after treatment without loss of efficacy.
Do not apply when the animal's hair coat is wet. However, shampooing or soaking the animal 2 or more hours after treatment will not reduce the efficacy of the product.
For ear mite treatment, do not apply directly to the ear canal.
It is important to apply the dose as indicated to minimise the quantity that the animal can lick off. If significant licking does occur, a brief period of hypersalivation may rarely be observed in cats.

4.5 Special precautions for use

Special precautions for use in animals

This veterinary medicinal product is to be applied to the skin surface only. Do not administer orally or parenterally.

Keep treated animals away from fires and other sources of ignition for at least 30 minutes or until the hair coat is dry.

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

This product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.

The product is a skin and eye irritant.
Do not smoke, eat or drink while handling the product.
Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid direct contact with treated animals until the application site is dry. On the day of treatment, children must not handle treated animals and the animals should not be permitted to sleep with their owners, especially children. Used applicators should be disposed of immediately and not left within the sight or reach of children.

People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the product with caution.

Other precautions

Do not allow treated animals to bathe in water courses until at least two hours after treatment administration.

4.6 Adverse reactions (frequency and seriousness)

Use of the veterinary medicinal product in cats has on rare occasions been associated with a mild transient alopecia at the site of application. On very rare occasions transient focal irritation may also be observed. The alopecia and irritation are normally self-resolving, but symptomatic therapy may be applicable in some circumstances.

If significant licking occurs, a brief period of hypersalivation may rarely be observed in cats.

On rare occasions in cats and dogs, application of the veterinary medicinal product may produce a local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder. This is normal and will disappear typically within 24 hours of treatment administration and does not affect either the safety or efficacy of the veterinary medicinal product.

Very rarely, as with other macrocyclic lactones, reversible neurological signs, including seizures, have been observed after use of the veterinary medicinal product in both dogs and cats.

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).

4.7 Use during pregnancy, lactation or lay

The product can be used in breeding, pregnant and lactating cats and dogs.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product should be administered as a single application of a single dose delivering a minimum of 6 mg/kg selamectin. When concurrent infestations or infections in the same animal are to be treated with the veterinary medicinal product, only one application of the recommended 6 mg/kg dose should be administered at any one time. The appropriate length of the treatment period for individual parasites is specified below.

Administer in accordance with the following table:

Cats (kg)	Product	mg of selamectin dispensed	Potency (mg/ml)	nominal pipette size, ml
≤ 2.5	1 pipette of Chanhold 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25
2.6–7.5	1 pipette of Chanhold 45 mg for cats 2.6-7.5 kg	45	60	0.75
7.6–10.0	1 pipette of Chanhold 60 mg for cats 7.6-10 kg	60	60	1.0
>10		Appropriate combination of pipettes	60	Appropriate combination of pipettes

Dogs (kg)	Product	mg of selamectin dispensed	Potency (mg/ml)	nominal pipette size, ml
≤ 2.5	1 pipette of Chanhold 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25
2.6–5.0	1 pipette of Chanhold 30 mg for dogs 2.6-5.0 kg	30	120	0.25
5.1–10.0	1 pipette of Chanhold 60 mg for dogs 5.1-10.0 kg	60	120	0.5
10.1–20.0	1 pipette of Chanhold 120 mg for dogs 10.1-20.0 kg	120	120	1.0
20.1–40.0	1 pipette of Chanhold 240 mg for dogs 20.1-40.0 kg	240	120	2.0
40.1–60.0	1 pipette of Chanhold 360 mg for dogs 40.1-60.0 kg	360	120	3.0

> 60		Appropriate combination of pipettes	60/120	Appropriate combination of pipettes

Flea treatment and prevention (cats and dogs)

Following administration of the veterinary medicinal product, the adult fleas on the animal are killed, no viable eggs are produced, and larvae (found only in the environment) are also killed. This stops flea reproduction, breaks the flea lifecycle and may aid in the control of existing environmental flea infestations in areas to which the animal has access.

For the prevention of flea infestations, the veterinary medicinal product should be administered at monthly intervals throughout the flea season, starting one month before fleas become active. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will aid prevention of flea infestations in the litter up to seven weeks of age.

For use as part of a treatment strategy for flea allergy dermatitis the veterinary medicinal product should be administered at monthly intervals.

Prevention of heartworm disease (cats and dogs)

The veterinary medicinal product may be administered year-round or at least within one month of the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of the veterinary medicinal product and resumption of monthly dosing will minimise the opportunity for the development of adult heartworms. When replacing another heartworm preventive veterinary medicinal product in a heartworm disease prevention programme, the first dose of the veterinary medicinal product must be given within a month of the last dose of the former medication.

Treatment of roundworm infections (cats and dogs)

A single dose of the veterinary medicinal product should be administered.

Treatment of biting lice (cats and dogs)

A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites (cats)

A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites (dogs)

A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at the time of treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Treatment of hookworm infections (cats)

A single dose of the veterinary medicinal product should be administered.

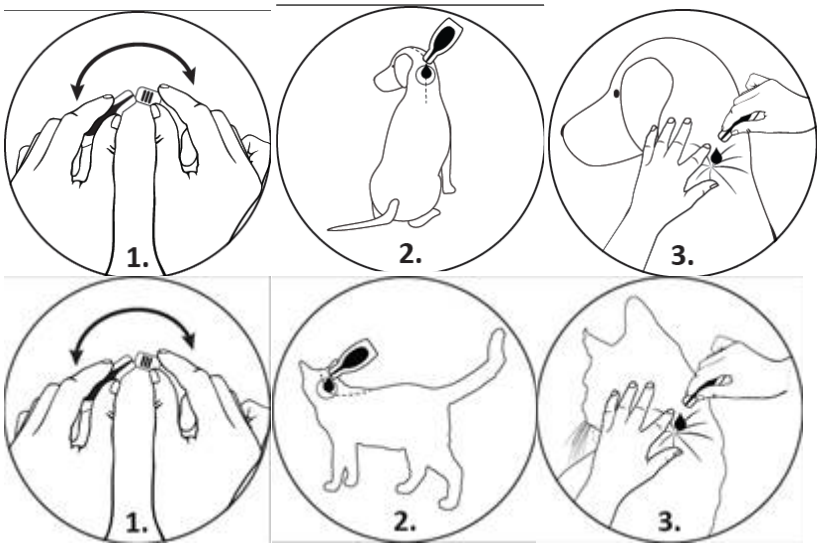
Treatment of sarcoptic mange (dogs)

For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

Method of administration:
Remove the product pipette from its protective package.
Hold the pipette upright.
Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.
Part the animal's coat at the base of the neck in front of the shoulder blades until the skin is visible.
Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.

Apply to the skin at the base of the neck in front of the shoulder blades.

Avoid contact between the product and your fingers.



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

No undesirable effects were observed after the administration of 10 times the recommended dose. Selamectin was administered at 3 times the recommended dose to cats and dogs infected with adult heartworms and no undesirable effects were observed. Selamectin was also administered at 3 times the recommended dose to breeding male and female cats and dogs, including pregnant and lactating females nursing their litters and at 5 times the recommended dose to ivermectin-sensitive Collies, and no undesirable effects were observed.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic products, insecticides and repellents, macrocyclic lactones. ATCvet code: QP54AA05.

5.1 Pharmacodynamic properties

Selamectin is a semi-synthetic compound of the avermectin class. Selamectin paralyses and/or kills a wide range of invertebrate parasites through interference with their chloride channel conductance causing disruption of normal neurotransmission. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods leading to their paralysis and/or death.

Selamectin has adulticidal, ovicidal and larvicidal activity against fleas. Therefore, it effectively breaks the flea life cycle by killing adults (on the animal), preventing the hatching of eggs (on the animal and in its environment) and by killing larvae (environment only). Debris from selamectin- treated pets kills flea eggs and larvae not previously exposed to selamectin and thus may aid in the control of existing environmental flea infestations in areas to which the animal has access.

Activity has also been demonstrated against heartworm larvae.

5.2 Pharmacokinetic particulars

Following spot on administration selamectin is absorbed from the skin reaching maximum plasma concentrations approximately 1 and 3 days after administration in cats and dogs respectively. Following absorption from the skin selamectin distributes systemically and is slowly eliminated from plasma as manifested in detectable plasma concentrations in dogs and cats 30 days after administration of a single topical dose at 6 mg/kg. The prolonged persistence and slow elimination of selamectin from plasma is reflected in the terminal elimination half-life values of 8 and 11 days in cats and dogs respectively. The systemic persistence of selamectin in plasma and the lack of extensive metabolism provide effective concentrations of selamectin for the duration of the inter-dosing interval (30 days).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxytoluene (E321)
Dipropylene glycol methyl ether
Isopropyl alcohol

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in a white plastic pipette formed from a layer of polypropylene/cyclic olefin copolymer/polypropylene with a layer of polyethylene/ethylene vinyl alcohol/polyethylene.

The product is available in packs of three pipettes (all strengths), six pipettes (all strengths except 15 mg), or fifteen pipettes (15 mg strength only) in individual foil sachets within an outer carton.
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

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. Containers and residual contents should be disposed of along with collected domestic refuse to avoid contamination of any water courses.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd,
Loughrea,
Co. Galway,
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/236/001-016

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17/04/2019

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

11 PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Chanelle Pharmaceuticals Manufacturing Ltd,
Loughrea,
Co. Galway,
Ireland

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Specific pharmacovigilance requirements:

Periodic safety update report (PSUR) submissions shall be synchronised and submitted at the same frequency as for the reference product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON, 15 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg
selamectin

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 15 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

3 pipettes,
15 pipettes

0.25 ml

5. TARGET SPECIES

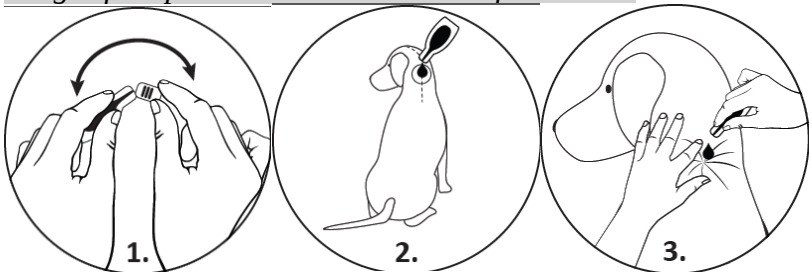
Cats and dogs weighing 2.5 kg or less

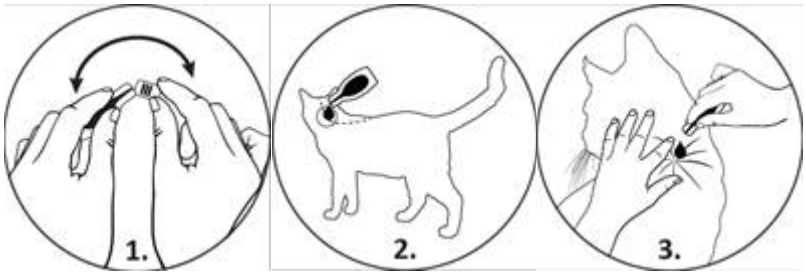
6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

Images for optional inclusion should space allow





8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Chanelle Pharmaceuticals Manufacturing Ltd,
Loughrea,
Co. Galway,
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/236/001
EU/2/19/236/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON, 30 mg, 60 mg, 120 mg, 240 mg, 360 mg for dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 30 mg spot-on solution for dogs 2.6–5.0 kg
Chanhold 60 mg spot-on solution for dogs 5.1–10.0 kg
Chanhold 120 mg spot-on solution for dogs 10.1–20.0 kg
Chanhold 240 mg spot-on solution for dogs 20.1–40.0 kg
Chanhold 360 mg spot-on solution for dogs 40.1–60.0 kg
selamectin

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 30 mg
Selamectin 60 mg
Selamectin 120 mg
Selamectin 240 mg
Selamectin 360 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

3 pipettes
6 pipettes

0.25 ml
0.5 ml
1.0 ml
2.0 ml
3.0 ml

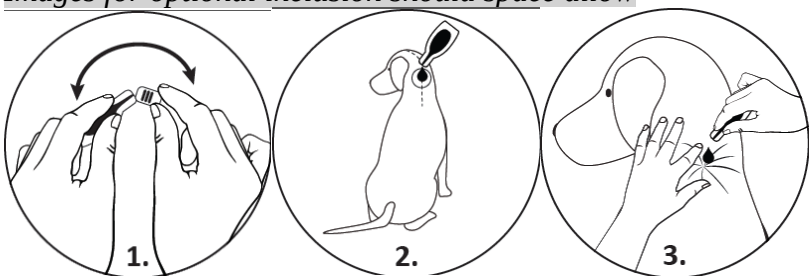
5. TARGET SPECIES

Dogs weighing 2.6–5.0 kg.
Dogs weighing 5.1–10.0 kg.
Dogs weighing 10.1–20.0 kg.
Dogs weighing 20.1–40.0 kg.
Dogs weighing 40.1–60.0 kg.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.
Images for optional inclusion should space allow



8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Chanelle Pharmaceuticals Manufacturing Ltd,
Loughrea,
Co. Galway,
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/236/007
EU/2/19/236/008
EU/2/19/236/009
EU/2/19/236/010
EU/2/19/236/011
EU/2/19/236/012
EU/2/19/236/013
EU/2/19/236/014
EU/2/19/236/015
EU/2/19/236/016

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON, 45 mg, 60 mg for cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 45 mg spot-on solution for cats 2.6–7.5 kg
Chanhold 60 mg spot-on solution for cats 7.6–10.0 kg
selamectin

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 45 mg
Selamectin 60 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

3 pipettes
6 pipettes

0.75 ml
1.0 ml

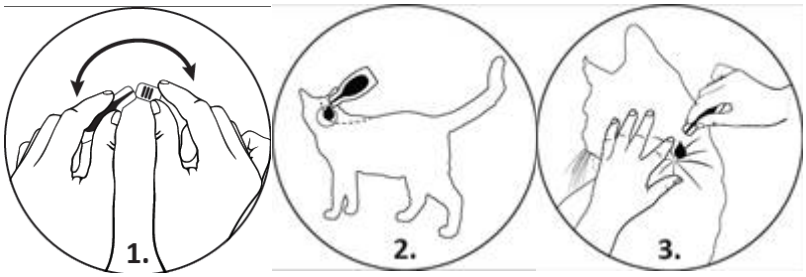
5. TARGET SPECIES

Cats weighing 2.6–7.5 kg.
Cats weighing 7.6–10.0 kg.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.
Images for optional inclusion should space allow



8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Chanelle Pharmaceuticals Manufacturing Ltd,
Loughrea,
Co. Galway,
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/236/003
EU/2/19/236/004
EU/2/19/236/005
EU/2/19/236/006

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FOIL LABEL/SACHET FOIL, 15 mg, 30 mg, 45 mg, 60 mg, 120 mg, 240 mg, 360 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg
Chanhold 30 mg spot-on solution for dogs 2.6–5.0 kg
Chanhold 45 mg spot-on solution for cats 2.6–7.5 kg
Chanhold 60 mg spot-on solution for cats 7.6–10.0 kg
Chanhold 60 mg spot-on solution for dogs 5.1–10.0 kg
Chanhold 120 mg spot-on solution for dogs 10.1–20.0 kg
Chanhold 240 mg spot-on solution for dogs 20.1–40.0 kg
Chanhold 360 mg spot-on solution for dogs 40.1–60.0 kg
selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

15 mg selamectin
30 mg selamectin
45 mg selamectin
60 mg selamectin
120 mg selamectin
240 mg selamectin
360 mg selamectin

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

4. ROUTE(S) OF ADMINISTRATION

Spot-on Use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE, 15 mg, 30 mg, 45 mg, 60 mg, 120 mg, 240 mg, 360 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 15 mg 
Chanhold 30 mg 
Chanhold 45 mg 
Chanhold 60 mg 
Chanhold 60 mg 
Chanhold 120 mg 
Chanhold 240 mg 
Chanhold 360 mg 
selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

15 mg selamectin
30 mg selamectin
45 mg selamectin
60 mg selamectin
120 mg selamectin
240 mg selamectin
360 mg selamectin

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

4. ROUTE(S) OF ADMINISTRATION

Spot-on Use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Chanhold spot-on solution

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

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd,
Loughrea,
Co. Galway,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg
Chanhold 30 mg spot-on solution for dogs 2.6–5.0 kg
Chanhold 45 mg spot-on solution for cats 2.6–7.5 kg
Chanhold 60 mg spot-on solution for cats 7.6–10.0 kg
Chanhold 60 mg spot-on solution for dogs 5.1–10.0 kg
Chanhold 120 mg spot-on solution for dogs 10.1–20.0 kg
Chanhold 240 mg spot-on solution for dogs 20.1–40.0 kg
Chanhold 360 mg spot-on solution for dogs 40.1–60.0 kg

selamectin

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

Each single-dose (pipette) delivers:

Chanhold 15 mg for cats and dogs	6% w/v solution	Selamectin	15 mg
Chanhold 30 mg for dogs	12% w/v solution	Selamectin	30 mg
Chanhold 45 mg for cats	6% w/v solution	Selamectin	45 mg
Chanhold 60 mg for cats	6% w/v solution	Selamectin	60 mg
Chanhold 60 mg for dogs	12% w/v solution	Selamectin	60 mg
Chanhold 120 mg for dogs	12% w/v solution	Selamectin	120 mg
Chanhold 240 mg for dogs	12% w/v solution	Selamectin	240 mg
Chanhold 360 mg for dogs	12% w/v solution	Selamectin	360 mg

Excipients:

Butylated hydroxytoluene (E321) 0.08%.
Clear colourless to yellow solution.

4. INDICATION(S)

Cats and dogs:

- **Treatment and prevention of flea infestations** caused by *Ctenocephalides* spp. for one month following a single administration. This is as a result of the adulticidal, larvicidal and

ovicidal properties of the product. The product is ovicidal for 3 weeks after administration. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will also aid in the prevention of flea infestations in the litter up to seven weeks of age. The product can be used as part of a treatment strategy for flea allergy dermatitis and through its ovicidal and larvicidal action may aid in the control of existing environmental flea infestations in areas to which the animal has access.

- **Prevention of heartworm disease** caused by *Dirofilaria immitis* with monthly administration.

The product may be safely administered to animals infected with adult heartworms, however, it is recommended, in accordance with good veterinary practice, that all animals 6 months of age or more living in countries where a vector exists should be tested for existing adult heartworm infections before beginning medication with the product. It is also recommended that dogs should be tested periodically for adult heartworm infections, as an integral part of a heartworm prevention strategy, even when the product has been administered monthly. This product is not effective against adult *D. immitis.*

- **Treatment of ear mites** (*Otodectes cynotis*).

Cats:
- Treatment of biting lice infestations (*Felicola subrostratus*)
- Treatment of adult roundworms (*Toxocara cati*)
- Treatment of adult intestinal hookworms (*Ancylostoma tubaeforme*).

Dogs:
- Treatment of biting lice infestations (*Trichodectes canis*)
- Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*)
- Treatment of adult intestinal roundworms (*Toxocara canis*).

5. CONTRAINDICATIONS

Do not use in animals under 6 weeks of age. Do not use in cats that are suffering from concomitant disease, or are debilitated and underweight (for size and age).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Use of the veterinary medicinal product in cats has on rare occasions been associated with a mild transient alopecia at the site of application. On very rare occasions transient focal irritation may also be observed. The alopecia and irritation are normally self-resolving, but symptomatic therapy may be applicable in some circumstances.

If significant licking does occur, a brief period of hypersalivation may rarely be observed in cats.

On rare occasions in cats and dogs, application of the veterinary medicinal product may produce a local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder. This is normal and will disappear typically within 24 hours of treatment administration and does not affect either the safety or efficacy of the veterinary medicinal product.

Very rarely, as with other macrocyclic lactones, reversible neurological signs, including seizures, have been observed after use of the veterinary medicinal product in both dogs and cats.

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).

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.

Other information

The product has been tested with no other adverse reactions in over 100 different pure and mixed breeds of dogs including Collies, and in mixed breeds and 16 pure breeds of cats.

7. TARGET SPECIES

Cats and dogs weighing 2.5 kg or less (Chanhold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg) Dogs weighing 2.6 kg–5.0 kg (Chanhold 30 mg spot-on solution for dogs 2.6–5.0 kg)
Cats weighing 2.6 kg–7.5 kg (Chanhold 45 mg spot-on solution for cats 2.6–7.5 kg)
Cats weighing 7.6 kg–10.0 kg (Chanhold 60 mg spot-on solution for cats 7.6–10.0 kg)
Dogs weighing 5.1 kg–10.0 kg (Chanhold 60 mg spot-on solution for dogs 5.1–10.0 kg)
Dogs weighing 10.1 kg–20.0 kg (Chanhold 120 mg spot-on solution for dogs 10.1–20.0 kg)
Dogs weighing 20.1 kg–40.0kg (Chanhold 240 mg spot-on solution for dogs 20.1–40.0 kg)
Dogs weighing 40.1 kg–60.0 kg (Chanhold 360 mg spot-on solution for dogs 40.1–60.0 kg)

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

Spot-on use.

Apply to the skin at the base of the neck in front of the shoulder blades.
The product should be administered topically as a single application of a single-dose delivering a minimum of 6 mg/kg selamectin. When concurrent infestations or infections in the same animal are to be treated with the veterinary medicinal product, only one application of the recommended 6 mg/kg dose should be administered at any one time. The appropriate length of the treatment period for individual parasites is specified below.

Administer the product in accordance with the following table:

Cats (kg)	Product	mg of selamectin dispensed	Potency (mg/ml)	Administered volume (nominal pipette size, ml)
≤ 2.5	1 pipette of Chanhold 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25

2.6–7.5	1 pipette of Chanhold 45 mg for cats 2.6-7.5 kg	45	60	0.75
7.6–10.0	1 pipette of Chanhold 60 mg for cats 7.6-10 kg	60	60	1.0
>10		Appropriate combination of pipettes	60	Appropriate combination of pipettes

Dogs (kg)	**Product**	**mg of selamectin dispensed**	**Potency (mg/ml)**	**Administered volume (nominal pipette size, ml)**
≤ 2.5	1 pipette of Chanhold 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25
2.6–5.0	1 pipette of Chanhold 30 mg for dogs 2.6-5.0 kg	30	120	0.25
5.1–10.0	1 pipette of Chanhold 60 mg for dogs 5.1-10.0 kg	60	120	0.5
10.1–20.0	1 pipette of Chanhold 120 mg for dogs 10.1-20.0 kg	120	120	1.0
20.1–40.0	1 pipette of Chanhold 240 mg for dogs 20.1-40.0 kg	240	120	2.0
40.1–60.0	1 pipette of Chanhold 360 mg for dogs 40.1-60.0 kg	360	120	3.0
> 60		Appropriate combination of pipettes	60/120	Appropriate combination of pipettes

Flea treatment and prevention (cats and dogs)

Animals older than six weeks of age:

Following administration of the veterinary medicinal product, the adult fleas on the animal are killed, no viable eggs are produced, and larvae (found only in the environment) are also killed. This stops flea reproduction, breaks the flea lifecycle and may aid in the control of existing environmental flea infestations in areas to which the animal has access.

For the prevention of flea infestations, the veterinary medicinal product should be administered to the animal at monthly intervals throughout the flea season, starting one month before fleas become active. This ensures that fleas infesting the animal are killed, no viable flea eggs are produced by these fleas, and larvae (found only in the environment) are also killed. This breaks the flea life cycle and prevents flea infestations.

For use as part of a treatment strategy for flea allergy dermatitis the veterinary medicinal product should be administered at monthly intervals.

Treatment of pregnant and lactating animals to prevent flea infestations in puppies and kittens:

Through a reduction in the flea population, monthly treatment of pregnant and lactating

animals will aid prevention of flea infestation in the litter up to seven weeks of age.

Prevention of heartworm disease (cats and dogs)

The veterinary medicinal product may be administered year-round or at least within one month of the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of the veterinary medicinal product and resumption of monthly dosing will minimise the opportunity for the development of adult heartworms. When replacing another heartworm preventive product in a heartworm disease prevention programme, the first dose of the veterinary medicinal product must be given within a month of the last dose of the former medication.

Treatment of roundworm infections (cats and dogs)

A single dose of the veterinary medicinal product should be administered.

Treatment of biting lice (cats and dogs)

A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites (cats)

A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites (dogs)

A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at each treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Treatment of hookworm infections (cats)

A single dose of the veterinary medicinal product should be administered.

Treatment of sarcoptic mange (dogs)

For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

9. ADVICE ON CORRECT ADMINISTRATION

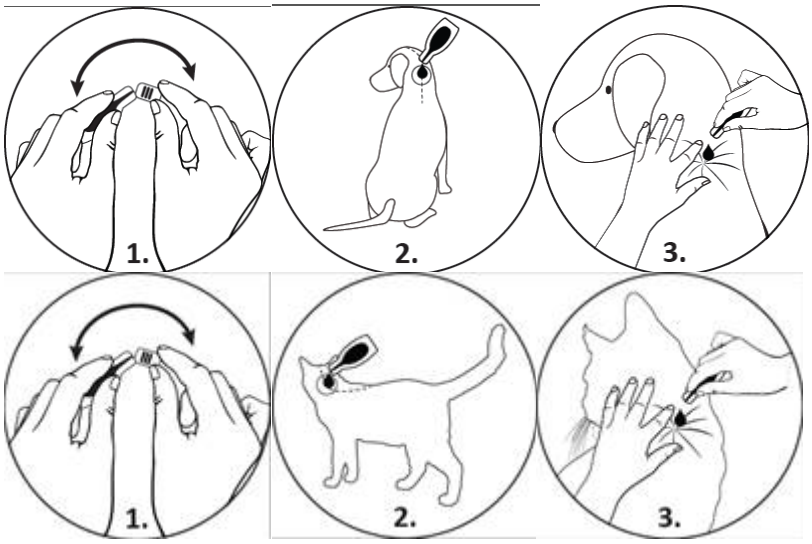
How to apply:
Hold the pipette upright.
Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.
Part the animal's coat at the base of the neck in front of the shoulder blades until the skin is visible.
Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents

completely and directly onto the skin in one spot.

Apply to the skin at the base of the neck in front of the shoulder blades.

Avoid contact between the product and your fingers.

Do not apply when the hair coat is wet. However, shampooing or soaking the animal 2 or more hours after treatment will not reduce the efficacy of the veterinary medicinal product.



10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Animals may be bathed 2 hours after treatment without loss of efficacy.
Do not apply when the animal's hair coat is wet. However, shampooing or soaking the animal 2 or more hours after treatment will not reduce the efficacy of the product.
For ear mite treatment, do not apply directly to the ear canal.
It is important to apply the dose as indicated to minimise the quantity that the animal can lick off.

Special precautions for use in animals:
This veterinary medicinal product is to be applied to the skin surface only. Do not administer orally or parenterally.
Keep treated animals away from fires and other sources of ignition for at least 30 minutes or until the hair coat is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.
The product is a skin and eye irritant.
Do not smoke, eat or drink while handling the product.
Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid direct contact with treated animals until the application site is dry. On the day of treatment, children must not handle treated animals and the animals should not be permitted to sleep with their owners, especially children. Used applicators should be disposed of immediately and not left within the sight or reach of children.
People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the product with caution.

Pregnancy:
Can be used in pregnant cats and dogs.

Lactation:
Can be used in lactating cats and dogs.

Fertility:
Can be used in breeding cats and dogs.

Interactions with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
No undesirable effects were observed after the administration of 10 times the recommended dose. Selamectin was administered at 3 times the recommended dose to cats and dogs infected with adult heartworms and no undesirable effects were observed. Selamectin was also administered at 3 times the recommended dose to breeding male and female cats and dogs, including pregnant and lactating females nursing their litters and at 5 times the recommended dose to ivermectin-sensitive Collies, and no undesirable effects were observed.

Incompatibilities
Not applicable.

Other precautions:
Do not allow treated animals to bathe in water courses until at least two hours after treatment administration.

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

Medicines should not be disposed of via wastewater.
Selamectin may adversely affect fish or certain water-borne organisms on which they feed.
Containers and residual contents should be disposed of along with collected domestic refuse

to avoid contamination of any water courses.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

The product is available in packs of three pipettes (all strengths), six pipettes (all strengths except 15 mg), or fifteen pipettes (15 mg strength only).

Not all pack sizes may be marketed.

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

België/Belgique/Belgien
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tél/Tel: +353 91 841788

Република България
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tél/Tel: +353 91 841788

Česká republika
Místní zástupce držitele rozhodnutí o registraci:
Orion Pharma s.r.o.
orion@orionpharma.cz

Danmark
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Deutschland
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Eesti
AS Dimedium
Roheline 9, Tahtvere,
61410 Tartu, Estonia
Tel: +372 739 0660

Ελλάδα
Neocell Ε.Π.Ε.
10ο χλμ. Εθνικής Οδού Αθηνών- Λαμίας
14451 Μεταμόρφωση, Αθήνα,
Tel: 210 2844333

España
Fatro Ibérica S.L.
Constitución 1, P.B. 3
08960 Sant Just Desvern
(Barcelona) España

Luxembourg/Luxemburg
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tél/Tel: +353 91 841788

Magyarország
Magyarországi képviselet:
Orion Pharma Kft.
1139 Budapest,
Pap Károly u. 4-6.,

Malta
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Nederland
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Norge
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Österreich
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Polska
Orion Pharma Poland Sp. z o.o.
ul. Fabryczna 5A,
00-446 Warszawa,
Poland
Tel: +48 22 833 31 77

Portugal
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

France
Laboratoire Perrigo France
200 Avenue De Paris
92320 Chatillon
France
Tél: +33 (0)1 55 48 18 00
Email : Chcifrlopfqualiteproduit@Perrigo.Com

Ireland
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Ísland
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Sími: + 353 91 841788

Italia
Azienda Terapeutica Italiana **A.T.I.** s.r.l.
Via Emilia, 285
Ozzano dell'Emilia (BO),
Italia

Κύπρος
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Τηλ: + 353 91 841788

Latvija
AS Dimedium Latvija
Ozolu iela 28, Jaunmarupe,
Marupes novads, LV-2166, Latvia
Tel: +371 67610001

Lietuva
Dimedium Lietuva UAB
Islandijos pl. 217-13, LT-49165
Kaunas, Lithuania
Tel: +370 615 64241

România
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Slovenija
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

Slovenská republika
Miestny zástupca držiteľa rozhodnutia o registrácii:
Orion Pharma s.r.o.
orion@orionpharma.sk

Suomi/Finland
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Puh/Tel: + 353 91 841788

Sverige
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788

United Kingdom (Northern Ireland)
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IE - Ireland
Tel: + 353 91 841788