

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE { CARTON, 360 mg for
dogs }**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 360 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains:

Selamectin 360 mg

3. PACKAGE SIZE

3 pipettes

6 pipettes

3.0 ml

4. TARGET SPECIES

Dogs weighing 40.1–60.0 kg.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 08749/5004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Sachet Foil, 360 mg}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 360 mg spot-on solution for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

360 mg selamectin

3. BATCH NUMBER


Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS { Pipette Foil, 360mg }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanhold 360 mg spot-on solution for dogs 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3.0 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Chanhold 360 mg spot-on solution for dogs 40.1–60.0 kg

2. Composition

Each pipette contains:

Active substances:

Selamectin 360 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylated hydroxytoluene (E321)	0.8 mg/ml

Clear colourless to yellow solution.

3. Target species

Dogs 

4. Indications for use

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*).**

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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

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 minimize the quantity that the animal can lick off.

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Please refer to section “Special precautions for disposal”

Other precautions:

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

Pregnancy and lactation:

Can be used in pregnant and lactating dogs.

Fertility:

Can be used in breeding dogs

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

No undesirable effects were observed after the administration of 10 times the recommended dose. Selamectin was administered at 3 times the recommended dose to 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 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.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	application site hair change ¹
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	neurological signs nos, seizures nos ²

¹ Local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder which typically disappear within 24 hours of treatment administration and does not affect either the safety or efficacy of the veterinary medicinal product.

² Reversible as with other macrocyclic lactones.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Spot-on use.

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:

Dogs (kg)	Product	mg of selamectin	Potency (mg/ml)	nominal pipette size, ml
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 (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 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

Method of administration:

Remove the product pipette from its protective package.

Hold the pipette upright.

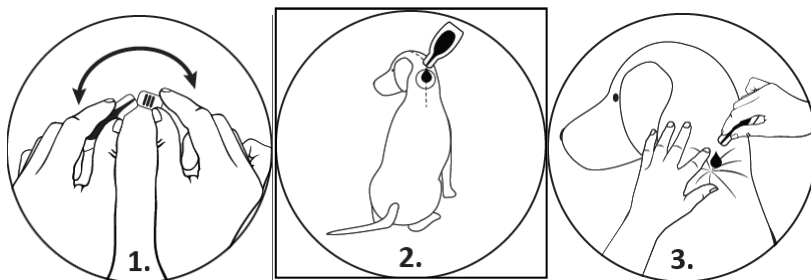
Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.

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.



10. Withdrawal periods

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, carton, after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

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.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 08749/5004

The product is available in packs of three pipettes, six pipettes in individual foil sachets within an outer carton.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

Tel: + 353 91 841788

vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Northern Ireland)

Chanelle Pharmaceuticals Manufacturing Ltd.

Loughrea

Co. Galway

IE - Ireland

Tel: + 353 91 841788

United Kingdom

Chanelle Vet UK Ltd

1 High Street

Hungerford

Berkshire

RG17 0DN – UK

Tel: + 44 1488 680664

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

17. Other information

POM-V

Gavin Hall
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