ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose (pipette) delivers:

Active substances:

EVICTO 15 mg for cats and dogs	60 mg/ml solution	Selamectin	15 mg
EVICTO 30 mg for dogs	120 mg/ml solution	Selamectin	30 mg
EVICTO 45 mg for cats	60 mg/ml solution	Selamectin	45 mg
EVICTO 60 mg for cats	60 mg/ml solution	Selamectin	60 mg
EVICTO 60 mg for dogs	120 mg/ml solution	Selamectin	60 mg
EVICTO 120 mg for dogs	120 mg/ml solution	Selamectin	120 mg
EVICTO 240 mg for dogs	120 mg/ml solution	Selamectin	240 mg
EVICTO 360 mg for dogs	120 mg/ml solution	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**
Butylhydroxytoluene	0.8 mg/ml
Dipropylene glycol methyl ether	
Isopropyl alcohol	

Colourless to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each 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 veterinary medicinal product. The veterinary medicinal 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 week of age. The veterinary

medicinal 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 area to which the animal has access.

- Prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration. The veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product has been administered monthly. This veterinary medicinal 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*).

3.3 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.

3.4 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 veterinary medicinal product.

For ear mite treatment, do not apply directly in the ear canal.

3.5 Special precautions for use

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.

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.

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

This veterinary medicinal product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition. Do not smoke, eat or drink while handling the veterinary medicinal product.

This veterinary medicinal product is a skin and eye irritant. Wash hands after use and wash off any veterinary medicinal product in contact with the skin immediately with soap and water. In case of 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 known hypersensitivity to selamectin should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:

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

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10 000 animals treated):	Application site alopecia[1,2], Application site hair change[3] Hypersalivation[4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Application site irritation[1,5] Neurological signs[6] (e.g. Seizure)

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Application site hair change[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Neurological signs[6] (e.g. Seizure)

[1] Normally self-resolving, but symptomatic therapy may be applicable in some circumstances.
[2] Mild and transient.
[3] 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.
[4] For a brief period, if significant licking does occur.
[5] Transient and focal.
[6] Reversible as with other macrocyclic lactones.

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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spot-on use.

The veterinary medicinal 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)**	**Administered volume (nominal pipette size, ml)**
≤ 2.5	1 pipette of Evicto 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25
2.6-7.5	1 pipette of Evicto 45 mg for cats 2.6-7.5 kg	45	60	0.75
7.6-10.0	1 pipette of Evicto 60 mg for cats 7.6-10.0 kg	60	60	1.0
> 10	Appropriate combination of pipettes	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 Evicto 15 mg for cats and dogs ≤2.5 kg	15	60	0.25
2.6-5.0	1 pipette of Evicto 30 mg for dogs 2.6-5.0 kg	30	120	0.25
5.1-10.0	1 pipette of Evicto 60 mg for dogs 5.1-10.0 kg	60	120	0.5
10.1-20.0	1 pipette of Evicto	120	120	1.0

	120 mg for dogs 10.1-20.0 kg			
20.1-40.0	1 pipette of Evicto 240 mg for dogs 20.1-40.0 kg	240	120	2.0
40.1-60.0	1 pipette of Evicto 360 mg for dogs 40.1-60.0 kg	360	120	3.0
> 60	Appropriate combination of pipettes	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/

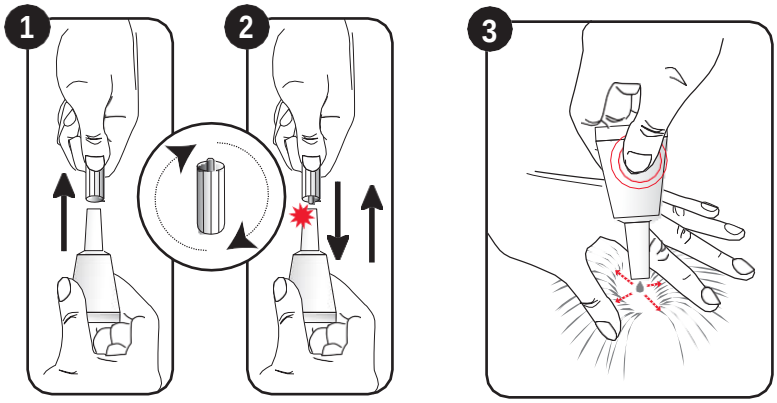
Treatment of hookworm infections (cats):

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.

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



How to apply:
Remove the veterinary medicinal product pipette from its protective package.

1 - Holding the pipette upright, remove the cap.
2 - Invert the cap and place other end back onto applicator tip. Push the cap down to break the applicator seal.
Remove the cap prior to treatment application.
3 - Part the hair at the base of your animal's neck in front of the shoulder blades to expose a small area of skin.
Apply the tip of the veterinary medicinal product pipette directly to the skin without massaging.
Squeeze the pipette firmly to empty the contents in one spot. Avoid contact between the veterinary medicinal product and your fingers.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No undesirable effects were observed after the administration of 10 times the recommended dose of selamectin.
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.

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

Not applicable.

4. PHARMACOLOGICAL PROPERTIES

4.1 ATCvet code: QP54AA05

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Store in the unopened sachet in a dry place in order to protect from light and moisture.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is available in packs of one, four and twenty-four (all pipette sizes).
The veterinary medicinal product is in polypropylene single-dose pipettes in an aluminium sachet overwrap.

1 pipette of EVICTO 15 mg for cats and dogs contains 0.25 ml of 60 mg/ml solution
1 pipette of EVICTO 45 mg for cats contains 0.75 ml of 60 mg/ml solution

1 pipette of EVICTO 60 mg for cats contains 1.0 ml of 60 mg/ml solution
1 pipette of EVICTO 30 mg for dogs contains 0.25 ml of 120 mg/ml solution
1 pipette of EVICTO 60 mg for dogs contains 0.5 ml of 120 mg/ml solution
1 pipette of EVICTO 120 mg for dogs contains 1.0 ml of 120 mg/ml solution
1 pipette of EVICTO 240 mg for dogs contains 2.0 ml of 120 mg/ml solution
1 pipette of EVICTO 360 mg for dogs contains 3.0 ml of 120 mg/ml solution.

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.

The veterinary medicinal product should not enter water courses as selamectin may be dangerous for fish and other aquatic organisms.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/242/001-024

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/07/2019

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 15 MG (1, 4 AND 24 PIPETTES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto 15 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 15 mg/pipette

3. PACKAGE SIZE

1 pipette
4 pipettes
24 pipettes

x 0.25 ml

4. TARGET SPECIES

Cats and dogs ≤ 2.5 kg

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the unopened sachet in a dry place in order to protect from light and moisture.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/242/001
EU/2/19/242/002
EU/2/19/242/003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 30 mg, 60 mg, 120 mg, 240 mg, 360 mg (1, 4 AND 24 PIPETTES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto 30 mg spot-on solution
Evicto 60 mg spot-on solution
Evicto 120 mg spot-on solution
Evicto 240 mg spot-on solution
Evicto 360 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 30 mg/pipette
Selamectin 60 mg/pipette
Selamectin 120 mg/pipette
Selamectin 240 mg/pipette
Selamectin 360 mg/pipette

3. PACKAGE SIZE

1 pipette
4 pipettes
24 pipettes

x 0.25 ml
x 0.5 ml
x 1.0 ml
x 2.0 ml
x 3.0 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the unopened sachet in a dry place to protect from light and moisture.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/242/010
EU/2/19/242/011
EU/2/19/242/012

EU/2/19/242/013
EU/2/19/242/014
EU/2/19/242/015

EU/2/19/242/016
EU/2/19/242/017
EU/2/19/242/018

EU/2/19/242/019
EU/2/19/242/020
EU/2/19/242/021

EU/2/19/242/022
EU/2/19/242/023
EU/2/19/242/024

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 45 mg, 60 mg (1, 4 AND 24 PIPETTES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto 45 mg spot-on solution
Evicto 60 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 45 mg/pipette
Selamectin 60 mg/pipette

3. PACKAGE SIZE

1 pipette
4 pipettes
24 pipettes

x 0.75 ml
x 1.0 ml

4. TARGET SPECIES

Cats 2.6–7.5 kg
Cats 7.6–10.0 kg

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

Store in the unopened sachet in a dry place to protect from light and moisture.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/242/004
EU/2/19/242/005
EU/2/19/242/006

EU/2/19/242/007
EU/2/19/242/008
EU/2/19/242/009

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto

≤ 2.5 kg
2.6–5.0 kg
2.6–7.5 kg
7.6–10.0 kg
5.1–10.0 kg
10.1–20.0 kg
20.1–40.0 kg
40.1–60.0 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each single-dose (pipette) delivers:

Active substances:

Evicto 15 mg for cats and dogs	60 mg/ml solution	Selamectin	15 mg
Evicto 30 mg for dogs	120 mg/ml solution	Selamectin	30 mg
Evicto 45 mg for cats	60 mg/ml solution	Selamectin	45 mg
Evicto 60 mg for cats	60 mg/ml solution	Selamectin	60 mg
Evicto 60 mg for dogs	120 mg/ml solution	Selamectin	60 mg
Evicto 120 mg for dogs	120 mg/ml solution	Selamectin	120 mg
Evicto 240 mg for dogs	120 mg/ml solution	Selamectin	240 mg
Evicto 360 mg for dogs	120 mg/ml solution	Selamectin	360 mg

Excipients:

Butylated hydroxytoluene 0.8 mg/ml.

Colourless to yellow solution.

3. Target species

Dogs and cats.

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 veterinary medicinal product. The veterinary medicinal 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 veterinary

medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product has been administered monthly. This veterinary medicinal 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. 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 veterinary medicinal product.
For ear mite treatment, do not apply directly to the ear canal.

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.
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.

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

This veterinary medicinal product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.
Do not smoke, eat or drink while handling the veterinary medicinal product.
This veterinary medicinal product is a skin and eye irritant. Wash hands after use and wash off any veterinary medicinal product in contact with the skin immediately with soap and water. In case of 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 known hypersensitivity to selamectin should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:

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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding animals.

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 of selamectin. 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.

7. Adverse events

Cats :

Rare (1 to 10 animals / 10 000 animals treated):
Application site alopecia (hair loss)[1,2], Application site hair change[3] Hypersalivation (increased salivation)[4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Application site irritation[1,5] Neurological signs[6] (e.g. Seizure)

Dogs :

Rare (1 to 10 animals / 10 000 animals treated):
Application site hair change[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Neurological signs[6] (e.g. Seizure)

[1]Normally self-resolving, but symptomatic therapy may be applicable in some circumstances.
[2] Mild and transient.
[3] 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.
[4] For a brief period, if significant licking does occur.
[5] Transient and focal.
[6] 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

Spot-on use.

Apply to the skin at the base of the neck in front of the shoulder blades.
The veterinary medicinal 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 veterinary medicinal 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 Evicto 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25
2.6-7.5	1 pipette of Evicto 45 mg for cats 2.6-7.5 kg	45	60	0.75
7.6-10.0	1 pipette of Evicto 60 mg for cats 7.6-10.0 kg	60	60	1.0
> 10	Appropriate combination of pipettes	Appropriate combination of pipettes	60	Appropriate combination of pipettes

Dogs (kg)	**Product**	**Mg of selamectin**	**Potency**	**Administered**

		dispensed	**(mg/ml)**	**volume (nominal pipette size, ml)**
≤ 2.5	1 pipette of Evicto 15 mg for cats and dogs ≤ 2.5 kg	15	60	0.25
2.6-5.0	1 pipette of Evicto 30 mg for dogs 2.6-5.0 kg	30	120	0.25
5.1-10.0	1 pipette of Evicto 60 mg for dogs 5.1-10.0 kg	60	120	0.5
10.1-20.0	1 pipette of Evicto 120 mg for dogs 10.1-20.0 kg	120	120	1.0
20.1-40.0	1 pipette of Evicto 240 mg for dogs 20.1-40.0 kg	240	120	2.0
40.1-60.0	1 pipette of Evicto 360 mg for dogs 40.1-60.0 kg	360	120	3.0
> 60	Appropriate combination of pipettes	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 to the animal, adult fleas and larvae are killed and no viable eggs are produced. This stops flea reproduction 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.

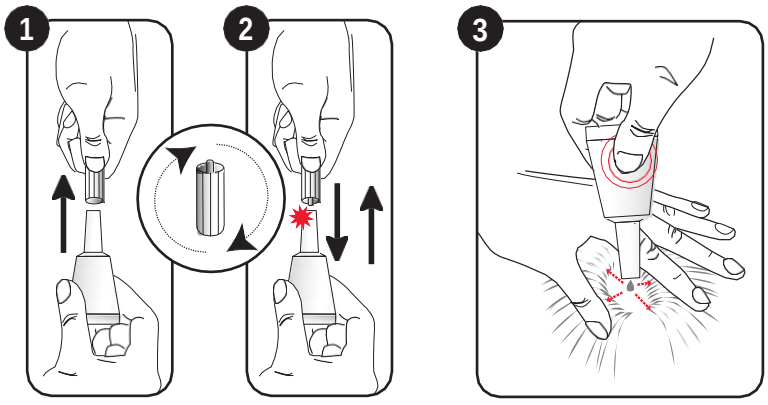
Treatment of hookworm infections (cats):

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



Remove the pipette from its protective package

1 - Holding the pipette upright, remove the cap.
2 - Invert the cap and place other end back onto applicator tip.
Push the cap down to break the applicator seal.
Remove the cap prior to treatment application.
3 - Part the hair at the base of your animal’s neck in front of the shoulder blades to expose a small area of skin.

Apply the tip of the pipette directly to the skin without massaging.
Squeeze the pipette firmly to empty the contents in one spot.
Avoid contact between the veterinary medicinal product and your fingers.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in the unopened sachet in a dry place to protect from light and moisture.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, sachet and 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 household waste.

This veterinary medicinal product should not enter water courses as selamectin may be dangerous for fish and other aquatic organisms.

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.

14. Marketing authorisation numbers and pack sizes

EU/2/19/242/001-024

1 pipette of Evicto 15 mg for cats and dogs contains 0.25 ml of 60 mg/ml solution
1 pipette of Evicto 45 mg for cats contains 0.75 ml of 60 mg/ml solution
1 pipette of Evicto 60 mg for cats contains 1.0 ml of 60 mg/ml solution
1 pipette of Evicto 30 mg for dogs contains 0.25 ml of 120 mg/ml solution
1 pipette of Evicto 60 mg for dogs contains 0.5 ml of 120 mg/ml solution
1 pipette of Evicto 120 mg for dogs contains 1.0 ml of 120 mg/ml solution
1 pipette of Evicto 240 mg for dogs contains 2.0 ml of 120 mg/ml solution
1 pipette of Evicto 360 mg for dogs contains 3.0 ml of 120 mg/ml solution.

The veterinary medicinal product is available in packs of one, four and twenty-four pipettes (all pipette sizes).
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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:

VIRBAC
1ère Avenue 2065 m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse events:

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

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