ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON 45mg (1, 4 AND 24 PIPETTES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto 45 mg spot-on solution for cats 2.6–7.5 kg
selamectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Selamectin 45 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 0.75 ml
4 x 0.75 ml
24 x 0.75 ml

5. TARGET SPECIES

Cat

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month, year}

11. SPECIAL STORAGE CONDITIONS

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

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5009

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Sachets 45mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto 45 mg spot-on solution for cats 2.6–7.5 kg

Selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

45 mg selamectin

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

0.75 mL (60 mg/mL)

4. ROUTE(S) OF ADMINISTRATION

Spot-on use

5. WITHDRAWAL PERIOD

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evicto 45 mg

2.6 – 7.5 kg
Selamectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

60 mg/ml

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

0.75 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

{number}

7. EXPIRY DATE

{month, year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Evicto 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:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

selamectin

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

	Volume of unit dose (ml)	Selamectin (mg)	Butylated hydroxytoluene (mg)
Evicto 45 mg for cats	0.75	45	0.6
Evicto 60 mg for cats	1.0	60	0.8

Colourless to yellow solution.

4. INDICATION(S)

- **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. This veterinary medicinal product is not effective against adult *D. immitis.*

- **Treatment of ear mites** (*Otodectes cynotis*).
- **Treatment of biting lice infestations** (*Felicola subrostratus*)
- **Treatment of adult roundworms** (*Toxocara cati*)
- **Treatment of adult intestinal hookworms** (*Ancylostoma tubaeforme*).

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

Mild transient alopecia at the site of application has been reported rarely after use of the veterinary medicinal product in cats. Transient focal irritation may also be observed. The alopecia and irritation are normally self-resolving, but symptomatic therapy may be applicable in some circumstances.

Local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder has been reported rarely. 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.

If significant licking does occur, a brief period of hypersalivation may rarely be observed in cats
As with other macrocyclic lactones, reversible neurological signs, including seizures, have been very rarely observed after use of the veterinary medicinal product.

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.

7. TARGET SPECIES

Cats.

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 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 7.6-10.0kg	60	60	1.0
> 10	Appropriate combination of pipettes	Appropriate combination of pipettes	60	Appropriate combination of pipettes

Flea treatment and prevention

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 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

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 program, 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

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

Treatment of biting lice

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

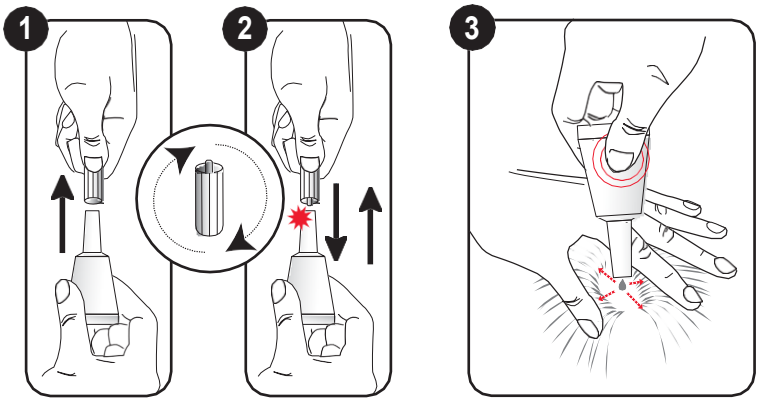
Treatment of ear mites

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

Treatment of hookworm infections

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

9. ADVICE ON CORRECT ADMINISTRATION



Remove the pipette from its protective package

1 - Holding the pipette upright, remove the cap.
Invert the cap and place other end back onto applicator tip.
Push the cap down to break the applicator seal.

2 - 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 product and your fingers.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions. Store in the unopened sachet in a dry place to protect from light and moisture.
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 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.

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.
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 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 product.

This product is a skin and eye irritant. 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 veterinary medicinal product with caution.

Pregnancy and lactation:
Can be used in pregnant and lactating cats.

Fertility:
Can be used in breeding cats.

Interaction 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 of selamectin. Selamectin was administered at 3 times the recommended dose to cats 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, including pregnant and lactating females nursing their litters, and no undesirable effects were observed.

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

January 2023

15. OTHER INFORMATION

Box of 1, 4 or 24 pipettes in individual foil overwraps.
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.

Approved: 13 April 2024