

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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

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:

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

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felisecto Plus 15 mg/2.5 mg spot-on solution for cats ≤ 2.5 kg

Selamectin/sarolaner

2. STATEMENT OF ACTIVE SUBSTANCES

15 mg selamectin/2.5 mg sarolaner

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

3 pipettes

0.25 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.

Read the package leaflet before use.



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

Store below 30 °C.
Do not remove the pipette from the blister until ready to use.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5024

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felisecto Plus 15 mg/2.5 mg spot-on solution for cats



≤2.5 kg

selamectin/sarolaner

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. 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

Felisecto Plus ≤ 2.5 kg

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

15 mg selamectin / 2.5 mg sarolaner

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

0.25 ml

4. ROUTE(S) OF ADMINISTRATION



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:
Felisecto Plus 15 mg/2.5 mg spot-on solution for cats ≤2.5 kg

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:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felisecto Plus 15 mg/2.5 mg spot-on solution for cats ≤2.5 kg

selamectin/sarolaner

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

Each unit dose (pipette) delivers:

Active substances:

Felisecto Plus spot-on solution	Total volume of unit dose (ml)	selamectin (mg)	sarolaner (mg)
Cats ≤2.5 kg	0.25	15	2.5

Excipients:

0.2 mg/ml butylated hydroxytoluene.

Spot-on solution.

Clear, colourless to yellow solution.

4. INDICATION(S)

For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks and one or more of the other target parasites is indicated at the same time.

Ectoparasites:

- For the treatment and prevention of flea infestations (*Ctenocephalides* spp.). The veterinary medicinal product has immediate and persistent flea killing activity against new infestations for 5 weeks. The product kills adult fleas before they lay eggs for 5 weeks. Through its ovicidal and larvicidal action, the veterinary medicinal product may aid in the control of existing environmental flea infestations in areas to which the animal has access.
- The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).
- Treatment of tick infestations. The veterinary medicinal product has immediate and persistent acaricidal effect for 5 weeks against *Ixodes ricinus* and *Ixodes hexagonus*, and 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.
- Treatment of ear mites (*Otodectes cynotis*).
- Treatment of biting lice infestations (*Felicola subrostratus*).

Ticks must attach to the host and commence feeding in order to be exposed to sarolaner.

Nematodes:

- Treatment of adult roundworms (*Toxocara cati*) and adult intestinal hookworms (*Ancylostoma tubaeforme*).
- Prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use in cats that are suffering from concomitant disease, or are debilitated and underweight (for size and age).

6. ADVERSE REACTIONS

Use of the veterinary medicinal product may result in mild and transient pruritus at the application site. Mild to moderate alopecia at the application site, erythema and drooling have been uncommonly observed.

Neurological signs (convulsions, ataxia) and gastrointestinal signs (emesis, diarrhoea) have been reported very rarely based on post-marketing safety experience. In most cases these signs are transient.

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.

Felisecto Plus should be administered as a single spot-on (topical) application in accordance with the following table (corresponding to a minimum of 6 mg/kg selamectin and 1 mg/kg sarolaner).

Bodyweight of cat (kg)	Pipette content (ml)	Strength and number of pipettes to be administered
		Felisecto Plus 15 mg/2.5 mg (yellow cap)
≤2.5	0.25	1

Fleas and ticks

For optimal control of tick and fleas infestations, the veterinary medicinal product should be administered at monthly intervals and continued throughout the flea and/or tick season based on local epidemiological situations.

Following administration of the product, the adult fleas on the animal are killed within 24 hours, 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.

Prevention of heartworm disease

The 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 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 product must be given within a month of the last dose of the former veterinary medicinal product.

Treatment of roundworm and hookworm infections

A single dose of the product should be administered. The need for and frequency of re-treatment should be in accordance with the advice of the prescribing veterinarian.

Treatment of biting lice

A single dose of the product should be administered.

Treatment of ear mites

A single dose of the product should be administered. Seek further veterinary examination 30 days after treatment to determine whether a second administration is necessary.

9. ADVICE ON CORRECT ADMINISTRATION

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

Do not apply when the animal's hair coat is wet.

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

It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product. If significant ingestion occurs, transient gastrointestinal effects such as hypersalivation, emesis, soft faeces or reduced food consumption may be observed and should normally resolve without treatment.

Apply topically to the skin at the base of the neck in front of the shoulder blades. The pipette should be removed from the protective package immediately prior to administration.

Holding the pipette upright, firmly depress the cap to puncture the applicator seal, then remove the cap.

Part the hair at the base of the cat'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 3–4 times to empty the contents in one spot. Avoid contact between the product and your fingers.



Transient cosmetic effects may occur at the application site such as temporary clumping or spiking of the hair, greasiness or dry white deposits, which normally resolve within 24 hours after product application. These effects do not affect the safety or 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.

Store below 30 °C.

Do not remove the pipette from the blister until ready to use.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Use of this veterinary medicinal product is indicated in cats aged at least 8 weeks old and weighing at least 1.25 kg bodyweight.

Ticks need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious tick-borne diseases cannot be excluded.

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 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 infection before beginning preventive use with the veterinary medicinal product.

This veterinary medicinal product is not effective against adult *D. immitis*. The administration to animals with adult heartworm infection did not pose safety concerns.

Whilst not routinely indicated, the potential benefits of performing periodic testing for heartworm infection in individual cases should be considered by the responsible veterinarian.

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

The product is harmful after ingestion. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Used pipettes should be disposed of immediately. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

The product may cause eye irritation. Avoid eye contact including hand-to-eye-contact. Avoid direct contact with treated animals until the application area is dry. 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 attention. People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the veterinary medicinal product with caution.

Children are not allowed to play with treated cats for 4 hours after treatment. It is recommended to treat animals in the evening. On the day of treatment, treated animals should not be permitted to sleep in the same bed as their owner, especially children.

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in animals intended for breeding. However, selamectin is considered safe for use in breeding, pregnant and lactating cats. While the safety of sarolaner has not been evaluated in breeding, pregnant or lactating cats, laboratory studies with sarolaner in rats and rabbits have not produced any evidence of teratogenic effects. Use only according to the benefit-risk assessment by the prescribing veterinarian.

Interactions with other medicinal products and other forms of interactions:

During clinical field testing, no interactions between this veterinary medicinal product and routinely used veterinary medicinal products were observed.

Overdose (symptoms, emergency procedures, antidotes):

No clinically significant adverse reactions were observed in kittens from 8 weeks of age treated with up to 5 times the maximum recommended dose of the product for up to 8 consecutive treatments at 28 day intervals, apart from a single cat administered 5 times the maximum dose that displayed transient hypersensitivity to touch, piloerection, mydriasis and mild tremor which resolved without treatment.

After accidental ingestion of a full product dose, transient gastrointestinal effects such as salivation, soft faeces, emesis, and reduced food consumption may occur, however these should resolve without treatment.

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 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 or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

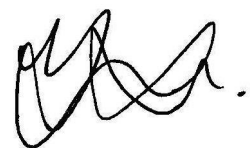
Selamectin is a semi-synthetic compound of the avermectin class. Selamectin has adulticidal, ovicidal and larvicidal activity against fleas. Therefore, it effectively breaks the flea life cycle by killing adults (on the animal), preventing the hatching of eggs (on the animal and in its environment) and 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. Selamectin is active against adult fleas (*Ctenocephalides* spp.) as well as mites (*Otodectes cynotis*), lice (*Felicola subrostratus*) and gastrointestinal nematodes (*Toxocara cati*, *Ancylostoma tubaeforme*). Activity has also been demonstrated against heartworm (*D. immitis*) larvae.

For fleas, the onset of efficacy is within 24 hours for 5 weeks after product application.

Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. Sarolaner is active against adult fleas (*Ctenocephalides* spp.) as well as several tick species such as *Dermacentor reticulatus*, *Ixodes hexagonus*, *Ixodes ricinus*, and *Rhipicephalus sanguineus*.

For ticks (*I. ricinus*), the onset of efficacy is within 24 hours of attachment for one month after product application.

The product is available in packs of three pipettes (all pipette sizes).



Approved: 17 August 2021