ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea 250 mg Spot-on solution for Large Dogs

imidacloprid

2. STATEMENT OF ACTIVE SUBSTANCES

Imidacloprid 250 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 2.5 ml
2 x 2.5 ml
3 x 2.5 ml
4 x 2.5 ml
6 x 2.5 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the prevention and treatment of flea infestations and for the treatment of biting lice *(Trichodectes canis)* on dogs from 10 kg to less than 25 kg body weight.
Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

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 every use for full instructions and user warnings.

User Warnings
Store pipettes in the original packaging until ready to use.
This product can cause mucous membrane, skin and eye irritation.
Therefore, contact of the product with mouth, skin and eyes should be avoided.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.
Do not smoke, drink or eat during application.
If contact with the skin occurs, wash hands with soap and water.
If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
Dispose of used pipettes immediately.
Wash hands after use.

Other Precautions
Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment.

10. EXPIRY DATE

EXP

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

EU Pharmaceuticals Ltd.
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER(S)

Vm 39787/4068

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea 250 mg Spot-on solution for Large Dogs

imidacloprid

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 250 mg

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

2.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on Use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP

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

Imidacloprid Spot-on 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 250 mg

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

2.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)

Not applicable

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:
Eziflea 250 mg Spot-on solution for Large Dogs

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:
EU Pharmaceuticals Ltd.
37 Geraldine Road
London
SW18 2NR

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea 250 mg Spot-on solution for Large Dogs
imidacloprid

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

Each 1 ml contains:

Active substance:
Imidacloprid 250 mg

Excipients:
Butylhydroxytoluene (E 321) 2.5 mg

4. INDICATION(S)

For the prevention and treatment of flea infestations and for the treatment of biting lice *(Trichodectes canis)* on dogs from 10 kg to less than 25 kg body weight.
Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

5. CONTRAINDICATIONS

Do not treat unweaned puppies of less than 8 weeks of age.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a sign of intoxication and

disappears within some minutes without treatment. (see also section 8 *Amounts to be administered and administration route*).
In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur.
Agitation and disorientation has also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have also been reported exceptionally in dogs.

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

Dogs

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

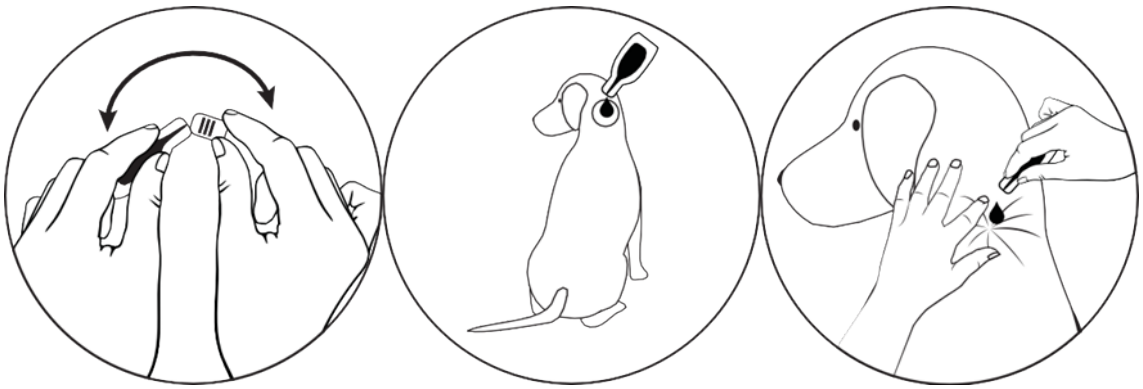
This product is for external use only and should not be administered orally. Animals should be weighed accurately prior to treatment.

Dosage and Treatment Schedule

Dog (kg body weight)	Product	Number of Pipettes	Advaprid (mg/kg body weight)
From 10 kg to less than 25 kg	Advaprid 250 for Dogs	1 x 2.5 ml	minimum of 10

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended.

The product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain.
However, in cases of frequent swimming or bathing re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not re-treat more frequently than once weekly.
In cases of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.
Method of administration:
Apply only to undamaged skin. 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. With the dog in the standing position, part the coat between 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.
Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.
Correct application will minimise the opportunity for the animal to lick the product.



9. ADVICE ON CORRECT ADMINISTRATION

Discard any opened pipettes.

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 carton and label after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
If signs of disease persist or appear, consult a veterinary surgeon.
This product is for topical use and should not be administered orally.
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
Do not allow recently treated animals to groom each other.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product can cause mucous membrane, skin and eye irritation.
Therefore, contact of the product with mouth, skin and eyes should be avoided.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.
Do not smoke, drink or eat during application.
If contact with the skin occurs, wash hands with soap and water.
If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
Dispose of used pipettes immediately.
Wash hands after use.

Pregnancy and lactation:
No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating bitches together with their offspring are limited.
Evidence so far suggests that no adverse effects are to be expected in these animals. Consult your veterinary surgeon before using in pregnant or nursing animals.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly onto the animal.

Overdose (symptoms, emergency procedures, antidotes):
No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.
In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

Incompatibilities:
None known.

Other Precautions
Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment.

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

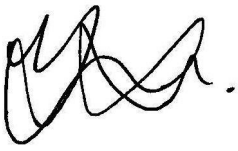
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box with 1, 2, 3, 4, 6 pipettes in individual foil sachets.
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