PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea Spot-on Solution Cat 50 mg
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

Fipronil 50 mg

3. PHARMACEUTICAL FORM

Spot-on Solution

4. PACKAGE SIZE

0.5 ml.
1, 2, 3, 4 or 6 pipettes in a carton.

5. TARGET SPECIES

Cats

6. INDICATION(S)

Treatment of flea (*Ctenocephalides* spp.) infestations. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides* spp.).
Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. If ticks of this species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they will be killed within a week.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical administration.
Read the package leaflet before use.
Dose: 1 pipette per cat.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.
Do not use in kittens less than 8 weeks old and/or weighing less than 1 kg.
Do not use in rabbits.

User Warnings
Please read before every use.
Keep pipettes in original packaging until ready to use.
This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.
Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product seek medical advice immediately.
Animals or people with a known hypersensitivity (allergy) to fipronil or any of the other ingredients should avoid contact with the product.
Treated animals should not be handled until the application site is dry, and children should not be allowed to 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 should not be allowed to sleep with owners, especially children.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.
Do not store above 25°C. Store in a dry place in the original package.
Discard any open pipettes.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Fipronil may adversely affect aquatic organisms. Medicines should not be disposed of via waste water but in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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 39787/4045

17. MANUFACTURER'S BATCH NUMBER

BN{number}

(For pack size of 3's the following shall also appear on the carton)

	Month 1:	Month 2:	Month 3:
Date:			

(For pack size of 6's the above plus the following shall appear on the carton):

	Month 4:	Month 5:	Month 6:
Date:			

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE UNIT

{0.5 ml pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea *50 mg* 
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg

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

0.5 ml

4. ROUTE OF ADMINISTRATION

Spot-on

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.

MINIMUM PARTICULARS TO APPEAR ON SACHET

SACHET FOIL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea Spot-on Solution *Cat 50 mg*
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

Note: Text in italics will be printed at production.

PACKAGE LEAFLET
Eziflea Spot-on Solution Cat 50 mg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder:
EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

Manufacturing Authorisation Holder responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eziflea Spot-on Solution Cat 50 mg
Fipronil

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

Each pipette contains:

Fipronil	50 mg
Butylhydroxyanisole E320	0.1 mg
Butylhydroxytoluene E321	0.05 mg

4. INDICATION(S)

Treatment of flea (*Ctenocephalides* spp.) infestations. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides* spp.). Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. If ticks of this species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they will be killed within a week.

5. CONTRAINDICATIONS

Do not use on kittens less than 8 weeks old and /or weighing less than 1 kg in the absence of available data.
Do not use on sick (e.g. systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
Do not use on animals with known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation (a lot of saliva in the cat's mouth) may be observed due mainly to the nature of the ingredients.
Among the extremely rare suspected adverse reactions, temporary skin reactions on the application site (skin discoloration, local hair loss, pruritus (hives, rash), erythema (redness)) and general pruritus (hives, rash) or hair loss have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia (oversensitivity), depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

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

Route of administration and dosage:
External use only.
Administer by topical application to the skin as follows:
1 pipette of 0.5 ml per cat.

Method of administration:
Remove the pipette from the sachet. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Snap back the tip.

Part the pet's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the cat's back, preferably at the base of the head and between the shoulder blades, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

9. ADVICE ON CORRECT ADMINISTRATION

Application of the solution as directed minimises the possibility that the animal will lick the solution off.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24-48 hours post application. There is little evidence available from studies with this product in cats; however from studies in dogs, crystals may be seen on the hair and slight scaling may occur within 24-48 hours after application.

Treatment schedule:
For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

The minimum interval between two treatments is four weeks.

Discard any opened pipettes.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not use after expiry date stated on the label.
Do not store above 25°C. Store in a dry place in the original package.
Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

The product does not prevent ticks from attaching to the animals. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

For optimal control of flea infestation in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

The product prevents re-infestation with all stages of ticks (*Dermacentor Reticulatus)* for four weeks, depending on the level of environmental challenge.

Special precautions for use in animals
Animals should be weighed accurately prior to treatment.

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment

Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested

Do not apply the product on wounds or damaged skin.

Use during pregnancy and lactation: Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

Interaction with other medicinal products and other forms of interaction: None known.

The toxicity of the veterinary medicinal product when administered to the skin is very low. The risk of experiencing adverse effects may increase in cases of overdose, so animals should always be treated with the correct product according to species and body weight.

User warnings
Keep pipettes in original packaging until ready to use.
This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product seek medical advice immediately.
Animals or people with a known hypersensitivity (allergy) to fipronil or any of the other ingredients should avoid contact with the product.
Treated animals should not be handled until the application site is dry, and children should not be allowed to 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 should not be allowed to sleep with owners, especially children.

Other precautions:
The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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.
Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Each pipette is enclosed in a foil sachet.

1, 2, 3, 4 or 6 pipettes in a carton.

Not all pack sizes may be marketed.
For animal treatment only.

Approved 27 April 2023