A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerotal Plus 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs
Fipronil/(S)-methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains:

Fipronil	402.00 mg
(S)-methoprene	361.80 mg

3. PHARMACEUTICAL FORM

Spot-on Solution

4. PACKAGE SIZE

1 x 4.02 ml
2 x 4.02 ml
3 x 4.02 ml
4 x 4.02 ml
5 x 4.02 ml
6 x 4.02 ml

5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

For external use only.

10. EXPIRY DATE

EXP {month/year}
Discard any open pipettes.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package.

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.

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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 39787/4118

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerotal Plus Spot-On 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 402 mg (S)-methoprene 361.8 mg

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

4.02 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.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerotal Plus 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs
Fipronil/(S)-methoprene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Zerotal Plus 402 mg/361.8 mg Spot-on Solution for Extra 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
EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

Site of Batch Release
Chanelle Pharmaceuticals Manufacturing Limited
Dublin Road
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerotal Plus 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs
Fipronil/(S)-methoprene

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

Each pipette contains:

Fipronil	402.00 mg
(S)-methoprene	361.80 mg

Excipients:

Butylhydroxyanisole (E320)	0.80 mg
Butylhydroxytoluene (E321)	0.40 mg

Clear amber solution.

4. INDICATION(S)

For the treatment of dogs weighing over 40 kg bodyweight:
- To be used against infestations with fleas, alone or in association with ticks and/or biting lice.
- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity) and larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.

- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

5. CONTRAINDICATIONS

In the absence of available data, do not use the product on puppies less than 8 weeks old and/or weighing less than 2 kg.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use in rabbits, as adverse reactions, including death, could occur.
In the absence of studies, the use of the product is not recommended in non-target species.
This product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Among the very rare suspected adverse reactions, transient skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.
If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.
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.
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).

7. TARGET SPECIES

Dogs.

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

One pipette of 4.02 ml (S) per dog weighing over 40 kg, corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

Do not overdose.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

Method of administration:
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. Part the coat on the back of the animal at the base of the neck in front of 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.

9. ADVICE ON CORRECT ADMINISTRATION

Discard any opened pipettes.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.
Store in the original package.

12. SPECIAL WARNING(S)

Special warnings:

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product. Emollient shampoos can be used prior to treatment but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 weeklong study.
There may be an attachment of a few ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
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.

Special precautions for use in animals:

Avoid contact with the animal's eyes.
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.

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

Keep the pipettes in the original packaging until ready to use and dispose of used pipettes immediately.
People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.
This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
After accidental ocular exposure the eye should be rinsed carefully with clean water. If eye irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.
Wash hands after use.
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 are not allowed to sleep with owners, especially children.
Do not smoke, drink or eat during application.

Other precautions:

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known

Overdose (symptoms, emergency procedures, antidotes):

No adverse effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of experiencing adverse effects (see section 6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

Incompatibilities:

Not applicable

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 product should be disposed of in accordance with local requirements.
Fipronil and (S)-methoprene should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

1, 2, 3, 4, 5 or 6 pipettes in individual foil sachets.
Not all pack sizes may be marketed.

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Approved 12 November 2021