A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaFlea Combo 402 mg/361.80 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 (40-60kg).

6. INDICATIONS

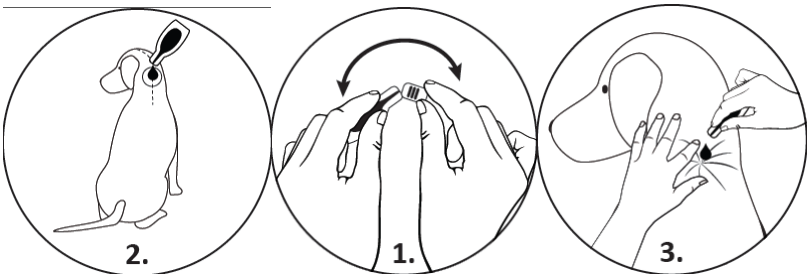
For the treatment of dogs weighing 40 to 60 kg bodyweight:

- Kills fleas on treated dogs for up to 8 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 8 weeks.
- Kills ticks on treated dogs for up to 4 weeks.
-Treats infestations with biting lice.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet carefully before each use. Keep the leaflet and any unopened sachets in the carton until required.

External use only, topical spot-on application to the skin. One pipette should be used for each dog weighing over 40 and up to 60 kg.



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. Always leave a minimum period of 4 weeks between treatments. Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet carefully before each use.

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 (allergy) to the active substances (Fipronil and (S)-methoprene) or to any of the excipients (ingredients).

User Warnings

This product can cause mucous membrane, skin and eye irritation. Avoid getting the product on your skin, or in your mouth or eyes. If the product gets into your eyes, immediately rinse the eyes with clean water.

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Treated animals should not be handled or played with 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.

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.
Do not smoke, drink or eat during application.
Wash hands after use.

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

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

Dispose of waste material 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.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
AVM-GSL

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 39787/4133

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TermaFlea Combo Spot-on
Fipronil/(S)-methoprene

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

TermaFlea Combo 402 mg/361.80 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:
TermaFlea Combo 402 mg/361.80 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

TermaFlea Combo 402 mg/361.80 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)

To be used against infestations with fleas, alone or in association with ticks and/or biting lice. For the treatment of dogs weighing 40-60 kg bodyweight:

- Kills fleas (*Ctenocephalides* spp.) on treated dogs for up to 8 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 8 weeks.

- Kills ticks (*Ixodes ricinus, Dermacentor variabilis, Dermacentor reticulatus, Rhipicephalus sanguineus*) on treated dogs for up to 4 weeks.
- Treats infestations with biting lice (*Trichodectes canis*).

5. CONTRAINDICATIONS

Do not use the product on puppies less than 8 weeks old and/or weighing less than 2 kg.
Do not use on sick or convalescent animals.
Do not use in rabbits, as adverse reactions, including death, could occur.
This product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.
In the absence of safety studies, the minimum treatment interval is 4 weeks. In the absence of studies, the use of the product is not recommended in non-target species. Do not use in known cases of hypersensitivity (allergy) to the active substances (Fipronil or (S)-methoprene) or to any of the excipients (ingredients).

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 a dog licks the product, it may cause them to salivate or drool for a brief period of time.

If you notice any side effects, even those not already listed in this package leaflet oryou think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively, you can report via your national reporting system.

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. (40-60kg).

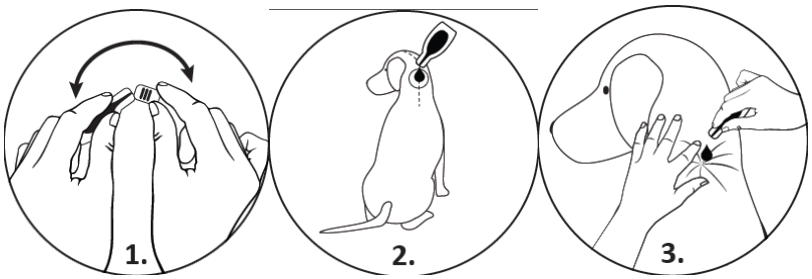
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

External use only, topical spot-on application to the skin

One pipette should be used for each dog weighing over 40 kg and up to 60 kg, applied to the skin as directed below.

How to use this product:

1. Hold the pipette in an upright position.
2. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette.
3. Snap back the tip of the pipette.
4. 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.
5. 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.



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. Always leave a minimum period of 4 weeks between treatments.

Do not overdose. Temporary changes to the coat (clumped/greasy hair) may be noted at theapplication site.

9. ADVICE ON CORRECT ADMINISTRATION

Discard any opened pipettes. Animals should be weighed accurately prior to use.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Store the product in the original sachet and carton until use.
Keep out of the sight and reach of children.
Do not store above 30°C.

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 week long study.

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. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time.

Special precautions for safe use in the target species:
For external use only. Do not administer orally. Avoid contact with the animal's eyes. If the product is in contact with eyes, rinse immediately with plenty of water. Do not apply the product on wounds or skin lesions. It is important to make sure that the veterinary medicinal product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

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.

Special precautions to be taken by the person administering the veterinary medicinalproduct 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. Avoid getting the product on your skin, or in your mouth or eyes.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
If the product gets into your eyes, immediately flush the eyes with water. If eye irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.

Treated animals should not be handled or played with until the application site is dry. It is therefore recommended that animals are 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. Wash hands after use.

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.

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

Pregnancy and lactation:
The product can be used during pregnancy and lactation.

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

Overdose:

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 4.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

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

August 2023

15. OTHER INFORMATION

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

AVM-GSL

Approved 18 August 2023