A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK Flea & Tick Treatment Plus for Extra Large Dogs 402 mg/361.8 mg Spot-on Solution (Fipronil and 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
6 x 4.02 ml

5. TARGET SPECIES

Dogs

6. INDICATIONS

Treats fleas, ticks and biting lice in dogs weighing over 40 kg.
Read the package leaflet carefully before each use. Keep the leaflet and any unopened sachets in the carton until required.

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on

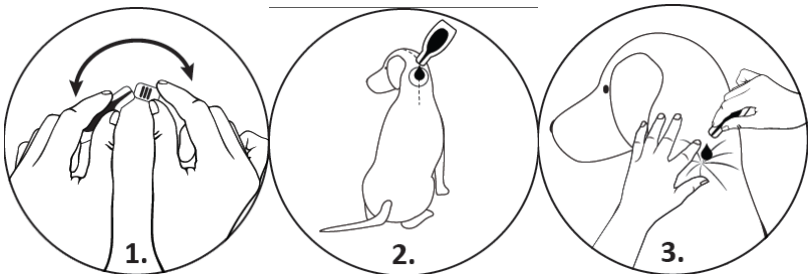
How to use this product:

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.

Images for optional inclusion on the carton



8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

For external use only. Read the package leaflet carefully before each use.
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.
If the product is accidently swallowed, seek medical advice immediately and show the package leaflet to the physician.
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

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.

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

Distributor:
VetUK Limited
Units 7 & 8 Europark, Station Road,
Thirsk, North Yorkshire YO7 1GQ

16. MARKETING AUTHORISATION NUMBER

Vm 39787/4022

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK Flea & Tick
Treatment Plus
Fipronil/(S)-methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil (S)-methoprene

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

VetUK Flea & Tick Treatment Plus for Extra Large Dogs 402 mg/361.8 mg Spot-on Solution (Fipronil and S-Methoprene)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
VetUK Flea & Tick Treatment Plus for Extra Large Dogs 402 mg/361.8 mg Spot-on Solution (Fipronil and S-Methoprene)

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

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

Distributor:
VetUK Limited
Units 7 & 8 Europark, Station Road,
Thirsk, North Yorkshire YO7 1GQ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK Flea & Tick Treatment Plus for Extra Large Dogs 402 mg/361.8 mg Spot-on Solution (Fipronil and S-Methoprene)
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

4. INDICATION(S)

- 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 on puppies less than 8 weeks old.
Do not use on sick or convalescent animals.
Do not use in rabbits, as adverse drug reactions including death, could occur.
This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.
Do not use in known cases of hypersensitivity (allergy) to any of the ingredients.

6. ADVERSE REACTIONS

In rare cases reactions of the skin at 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 or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

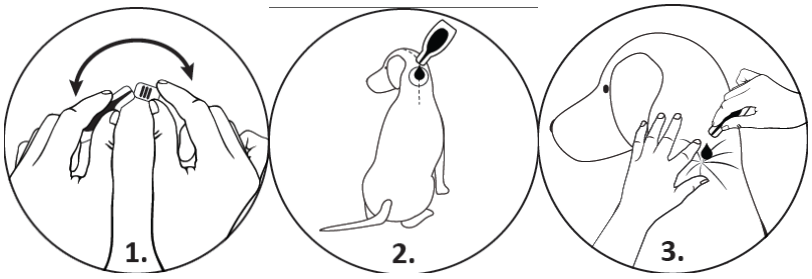
Dogs.

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

One pipette should be used for each dog weighing over 40 kg, applied to the skin as directed below.
In the absence of safety studies, the minimum treatment interval is 4 weeks.

<u>How to use this product:</u>

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

9. ADVICE ON CORRECT ADMINISTRATION

Discard any opened pipettes.

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 precautions for use in animals:

Avoid contact with the animal's eyes.
It is not recommended to bath animals within 2 days after application of the product.
There may be an attachment of single 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 to be taken by the person administering the veterinary medicinal product to animals:

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. If the product is accidently swallowed, seek medical advice immediately and show the package leaflet to the physician.

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.
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):

The risk of experiencing adverse effects (see Section 6. Adverse Reactions) may increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight. If you administer too much of the product there may be a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application. Itching may also occur at the treatment spot.

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

June 2021

15. OTHER INFORMATION

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

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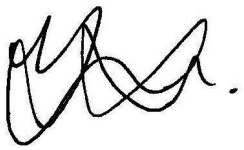

Approved: 09 March 2023