A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

On Defence Flea + Tick Spot-on Solution for Cats 50 mg/60 mg
Fipronil/(S)-methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains:

Fipronil	50.00 mg
(S)-methoprene	60.00 mg

3. PHARMACEUTICAL FORM

Spot-on Solution

4. PACKAGE SIZE

1 x 0.5 ml
2 x 0.5 ml
3 x 0.5 ml
4 x 0.5 ml
6 x 0.5 ml

5. TARGET SPECIES

Cats

6. INDICATIONS

Treats fleas, ticks and biting lice.
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

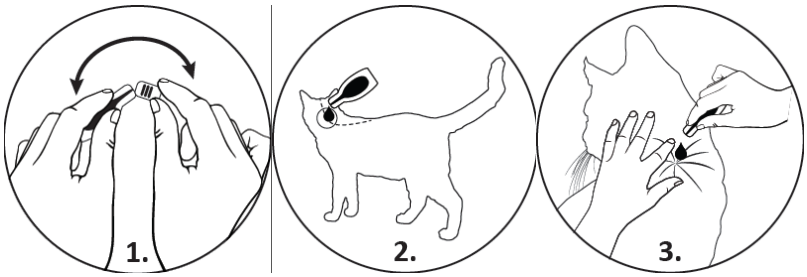
Spot-on.
How to use this product:

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.

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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/3078

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

On Defence

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil (S)-methoprene

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

0.5 ml

4. ROUTE(S) 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 BLISTERS OR STRIPS

{Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

On Defence Flea + Tick Spot-on Solution for Cats 50 mg/60 mg
Fipronil/(S)-methoprene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing 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:
On Defence Flea + Tick Spot-on Solution for Cats 50 mg/60 mg

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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

On Defence Flea + Tick Spot-on Solution for Cats 50 mg/60 mg
Fipronil/(S)-methoprene

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

Each pipette contains:

Fipronil	50.00 mg
(S)-methoprene	60.00 mg

Excipients:

Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg

Clear amber solution.

4. INDICATION(S)

- Kills fleas (*Ctenocephalides* spp.) on treated cats for up to 4 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 6 weeks.
- Kills ticks (*Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus*) on treated cats for up to 2 weeks.
- Treats infestations with biting lice (*Felicola subrostratus*).

5. CONTRAINDICATIONS

Do not use on kittens less than 8 weeks old and/or weighing less than 1 kg.
Do not use on sick or convalescent animals.
Do not use in rabbits, as adverse drug reactions, including death, could occur.
Do not use in known cases of hypersensitivity (allergy) to any of the ingredients.

6. ADVERSE REACTIONS

In very rare cases reactions of the skin at the application site (scaling, 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) or vomiting have also been observed after use. If a cat licks the product, it may cause them to salivate or drool for a brief period of time. If you notice any side serious effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

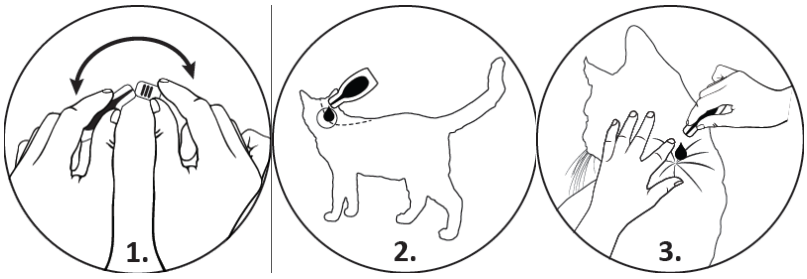
7. TARGET SPECIES

Cats.

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

One pipette should be used for each cat, 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.

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 each target species:

Avoid contact with the animal's eyes.

Special precautions for use in animals:

No information is available on the effect of bathing/shampooing on how well the treatment may work in cats. However, based on information available for dogs, 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.
Consult for veterinary surgeon before using the product on animals in contact with kittens that are less than 8 weeks old.

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.

Pregnancy and lactation:

Cats

The product can be used during pregnancy. Consult for veterinary surgeon before using the product on animals in contact with kittens that are less than 8 weeks old.

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 with overdosing .

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

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

AVM-GSL

Gavin Hall
Approved: 29 September 2025