A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Guardian Plus Spot-On Solution for Cats
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
6 x 0.5 ml

5. TARGET SPECIES

Cats

6. INDICATIONS

Kills fleas on treated cats for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks.
Kills ticks on treated cats for up to 2 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.

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. 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

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 the active substances (Fipronil or (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.

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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/5075

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Guardian Plus Spot-On

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 50 mg (S)-methoprene 60 mg

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

Johnson's Guardian Plus Spot-On Solution for Cats
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:
Johnson's Guardian Plus Spot-On Solution for Cats

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

Marketing Authorisation Holder
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Guardian Plus Spot-On Solution for Cats
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)

To be used against infestations with fleas, alone or in association with ticks and/or biting lice:

Kills fleas (*Ctenocephalides* spp.) on treated cats for up to 4 weeks and prevents eggs laid by 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 the product 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 the active substances (Fipronil or (S)-methoprene) or to any of the excipients (ingredients). 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.

6. ADVERSE REACTIONS

Cats
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.
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).

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 effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Cats.

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 cat, applied to the skin as directed below.

<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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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

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:

Other animals living in the same household should also be treated with a suitable product. No data on the effect of bathing/shampooing on the efficacy of the product in cats are available. However, based on information available for dogs shampooed as from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

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. Animals should be weighed accurately prior to treatment.
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.

No information is available on the effect of bathing/shampooing on how well the treatment may work. 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.

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:

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, avoid getting the product on your skin, or in your mouth or eyes. 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.
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 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:

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

Use during pregnancy and lactation:

The product can be used during pregnancy. The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented.

Special care should be taken in this case

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Interaction with other medicinal products:

Do not use simultaneously with other flea products which are applied directly on to the animal.

Overdose:

The risk of experiencing adverse effects may increase with overdosing.

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.
Itching may occur following treatment.
Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

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 or 6 pipettes in individual foil sachets.
Not all pack sizes may be marketed.

AVM-GSL

Distributor and Local Representative

Johnson' Veterinary Products Ltd
Reddicap Trading Estate
Sutton Coldfield
West Midlands
B75 7DF
Tel: +44(0)121 378 1684
info@johnsons-vet.com

Gavin Hall
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