ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1, 2, 3, 4 or 6 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLEASOLVE 50 mg spot-on solution for cats
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCE

One 0.5 ml pipette contains 50 mg of fipronil

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1, 2, 3, 4 or 6 pipettes

5. TARGET SPECIES

Cats.

6. INDICATIONS

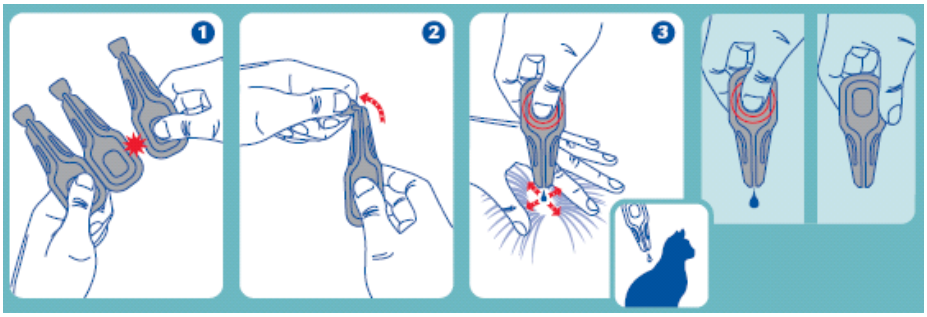
Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.
The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides felis*).
The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (*Rhipicephalus sanguineus, Ixodes ricinus, Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

7. METHOD AND ROUTE OF ADMINISTRATION

External use only.
Administer by topical application to the skin 1 pipette of 0.5 ml per animal.
Read package leaflet before use.

Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.

Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the cat's back, preferably at the base of the head and between the shoulders.



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.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.
White deposits may also be seen at the site for up to 48 hours after application.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS

Do not remove from blister until required for use.
User safety – please read before every use.
This product can cause mucous membrane and eye irritation. Therefore, do not get the product in your mouth or eyes.
In the case of accidental eye contact, immediately rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the packaging to the doctor.
Avoid contents coming into contact with the fingers. If this occurs, quickly wash hands with soap and water. Wash hands after use.
Do not smoke, drink or eat during application.
People with known hypersensitivity (allergy) to Fipronil or the other ingredients should avoid contact with this product.
Treated animals should not be handled or played with until the application site is dry. It is therefore recommended that the animals should be treated during the early evening, and recently treated animals should not be allowed to sleep with owners, especially children.

10. EXPIRY DATE

EXP : {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 30°C. Store in a dry place. Store in the original package.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

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

Naqua Ltd
Laboratory E12, Ground Floor
East Block, Building 500
Discovery Park, Ramsgate Road
Sandwich
Kent
CT13 9ND
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 49507/4002

17. MANUFACTURER'S BATCH NUMBER

Batch : {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1 blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLEASOLVE

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSE

50 mg

3. ROUTE(S) OF ADMINISTRATION

(reference is made to the cat logo and drop in section 1)

4. EXPIRY DATE

EXP : {month/year}

5. BATCH NUMBER

Batch : {number}

6. MARKETING AUTHORISATION HOLDER

Naqua Ltd

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

1 pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLEASOLVE

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSE

50 mg

3. ROUTE(S) OF ADMINISTRATION

(reference is made to the cat logo and drop in section 1)

4. EXPIRY DATE

EXP : {month/year}

5. BATCH NUMBER

Batch : {number}

6. MARKETING AUTHORISATION HOLDER

Naqua Ltd

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

FLEASOLVE 50 mg 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 and manufacturer responsible for batch release:
Naqua Ltd
Laboratory E12, Ground Floor
East Block, Building 500
Discovery Park, Ramsgate Road
Sandwich
Kent
CT13 9ND
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLEASOLVE 50 mg spot-on solution for cats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One 0.5 ml pipette contains:

Active substance:	
Fipronil	50 mg
Excipients:	
Butylhydroxyanisole E320	0.1 mg
Butylhydroxytoluene E321	0.05 mg

Clear, colourless to yellow solution.

4. INDICATIONS

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.
The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides felis*).
The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (*Rhipicephalus sanguineus, Ixodes ricinus, Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 2 months old and/or weighing less than 1 kg.
Do not use on sick (systemic diseases, fever…) or convalescent animals.

Do not use in rabbits, due to a risk of adverse drug reactions or even death.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Very rarely transient cutaneous reactions at the application site (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms) or vomiting have also been observed very rarely 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 you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

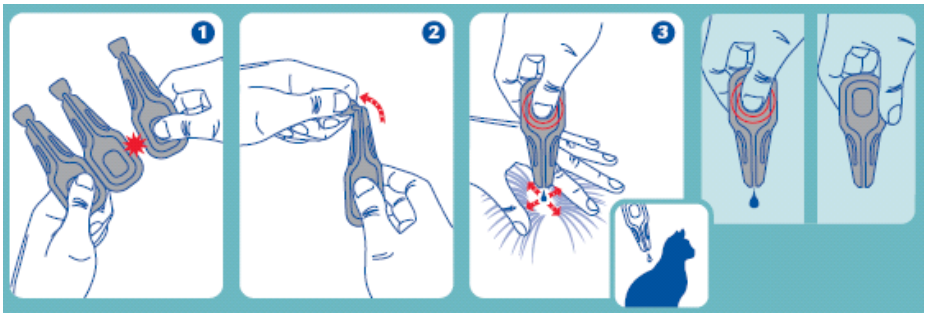
Cats.

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

Route of administration and dosage:
External use only.
Administer by topical application to the skin 1 pipette of 0.5 ml per animal.

Method of administration:
Thermoformed pipettes:
Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.

Part the pet’s coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the cat’s back, preferably at the base of the head and between the shoulders.



Polypropylene pipettes:

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.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.
White deposits may also be seen at the site for up to 48 hours after application.

9. ADVICE ON CORRECT ADMINISTRATION

Treatment schedule:

In the absence of safety studies, the minimum treatment interval is 4 weeks.
Please seek professional advice regarding the optimal treatment schedule for your pet.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30°C. Store in a dry place. Store in the original package.
Do not use after the expiry date stated on the pipette. The expiry date refers to the last day of that month.
Do not remove from blister until required for use.

12. SPECIAL WARNINGS

For animal treatment only
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.

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48

hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

It is advisable to avoid frequent bathing or shampooing because the maintenance of effectiveness of the product in these cases has not been tested.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats in the household are recommended.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Special precautions for use in animals
Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Keep pipettes in original packaging until ready to use

People with a known hypersensitivity to fipronil or excipients should avoid contact with the veterinary medicinal product.

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Avoid contents coming into contact with the skin. If this occurs, wash hands with soap and water.
Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product.
In case of accidental ingestion of product seek medical advice immediately.

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 should not be 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
Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

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 products should be disposed of in accordance with local requirements.
Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2024

Pack sizes:
Blister cards or boxes of 1,2,3,4 or 6 pipettes.
Not all pack sizes may be marketed.

14. OTHER INFORMATION

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Approved 23 February 2024