PARTICULARS TO APPEAR ON THE OUTER PACKAGE

FLEVOX SPOT ON DOG 20-40 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flevox 268 mg spot-on solution for large dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One pipette of 2.68 ml contains:

Fipronil	268 mg
Butylhydroxyanisole (E320)	1.072 mg
Butylhydroxytoluene (E321)	0.536 mg

3. PHARMACEUTICAL FORM

Spot on solution

4. PACKAGE SIZE

1 pipette of 2.68 ml
3 pipettes of 2.68 ml
6 pipettes of 2.68 ml
30 pipettes of 2.68 ml
36 pipettes of 2.68 ml
50 pipettes of 2.68 ml

5. TARGET SPECIES

Dog

6. INDICATIONS

Treatment of flea and biting/chewing lice infestations, control of Flea Allergy Dermatitis.
Read package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Read package leaflet before use

10. EXPIRY DATE

EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

No special storage precautions.

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

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4127

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER – FLEVOX SPOT ON DOG 20-40 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flevox 268 mg spot-on solution for large dogs
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE

Fipronil 268 mg

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

2.68 ml

4. ROUTES OF ADMINISTRATION

Pictogram of route of administration

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

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

PIPETTE – FLEVOX SPOT ON DOG 20-40 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flevox 268 mg spot-on solution for large dogs
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Pictogram of target specie, for animal treatment only, and pharmaceutical form.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Flevox 67 mg spot-on solution for small dogs
Flevox 134 mg spot-on solution for medium dogs
Flevox 268 mg spot-on solution for large dogs
Flevox 402 mg spot-on solution for very 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: (to be completed nationally)
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for Batch release:

VETOQUINOL BIOWET Sp. Z.o.o.
UL. KOSYNIERÓW GDYŃSKICH 13/14
66-400 GORZÓW WLKP
POLAND

Or

VETOQUINOL SA
MAGNY VERNOIS
F-70200 LURE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flevox 67 mg spot-on solution for small dogs
Flevox 134 mg spot-on solution for medium dogs
Flevox 268 mg spot-on solution for large dogs
Flevox 402 mg spot-on solution for very large dogs

Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 pipette contains:

	Flevox Small Dogs	Flevox Medium Dogs	Flevox Large Dogs	Flevox Very Large Dogs
Active substance Fipronil	67 mg	134 mg	268 mg	402 mg
Excipients: Butylhydroxyanisole (E320)	0.268 mg	0.536 mg	1.072 mg	1.608 mg

Butylhydroxytoluene (E321)	0.134 mg	0.268 mg	0.536 mg	0.804 mg

4. INDICATIONS

In dogs:
Treatment of flea (Ctenocephalides spp.) and biting/chewing lice (*Trichodectes canis)* infestations in dogs.

Insecticidal efficacy against new infestations with adult fleas persists for up to 8 weeks. Newly arriving fleas are killed within 48 hours of landing on the animal. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

The product has not demonstrated an immediate acaricidal effect against ticks but has demonstrated persistent acaricidal efficacy for up to 4 weeks against *Rhipicephalus sanguineus and Dermacentor reticulatus* and up to 3 weeks against *Ixodes Ricinus.* If ticks of these species 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

Do not use on puppies less than 8 weeks old and/or weighing less than 2 kg, in the absence of available data.
Do not use on sick (systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse drug reactions and even death could occur.
Do not use in case of hypersensitivity to fipronil or to any of the excipients.
Do not administer orally.
This product has been developed specifically for dogs. Do not use on cats as this could lead to overdosing.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia could occur after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs could be observed after use.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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

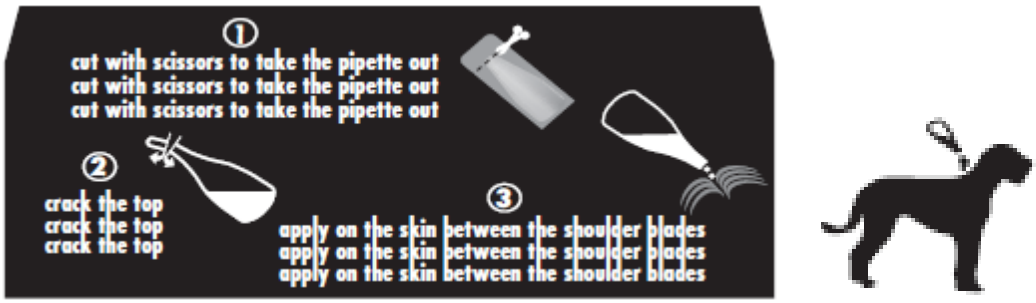
Dog.

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

For external use only.
Spot-on use.
Animals should be weighed accurately prior to treatment.
Apply topically:
*1 pipette of 0.67ml per dog weighing over 2kg and up to 10kg bodyweight
*1 pipette of 1.34ml per dog weighing over 10kg and up to 20kg bodyweight
*1 pipette of 2.68ml per dog weighing over 20kg and up to 40kg bodyweight
*1 pipette of 4.02ml per dog weighing over 40kg and up to 60kg bodyweight
For dogs over 60kg use two pipettes of 2.68ml

The minimum treatment interval is 4 weeks.

Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its content onto the skin.



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 generally disappear within 24 hours post application but can persist for up to 2 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. STORAGE PRECAUTIONS

This veterinary medicine does not require any special storage conditions.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton. This expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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.
Ticks already on the animal prior to treatment may not be killed within the first 48 hours after application of the product, but they may be killed within a week. Removal of ticks already on the animal at the time of application is recommended. The product does not prevent ticks from attaching to the animal. If the animal has been treated prior to exposure to the ticks, most ticks will be killed within 48 hours of infestation. 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.
No data on the effect of bathing/shampooing on the efficacy of the product are available. Therefore, bathing/immersion in water within 2 days of application and more frequent bathing than once a week should be avoided.
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.
When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

Special precautions for use in animals
Avoid contact with the animal's eyes. In case of accidental eye contact, rinse immediately with plenty of water.
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.
Do not apply the product on wounds or damaged skin.
Specific studies investigating the safety of the product following repeated administration have not been conducted due to the known safety profile of the active substance and excipients.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

In case of accidental eye contact, rinse immediately with plenty of water. If the irritation persists, seek medical advice and show the label or the package leaflet to the physician.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.
Do not smoke, drink or eat during application.
People with a known hypersensitivity to fipronil or any excipient should avoid contact with the product.
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.
Keep pipettes in the original packaging and dispose of used pipettes immediately.

Other precautions
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Use during pregnancy, lactation or lay
Laboratory studies using fipronil have not shown any teratogenic or embryotoxic effect. No study was conducted with this product on pregnant and lactating dogs. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
None known.

Overdose (symptoms, emergency procedures, antidotes), if necessary
No adverse effects were observed in target animal safety studies in dogs and puppies aged 8 weeks and older and weighing about 2 kg treated once up to five times the recommended dose. The risk of experiencing adverse effects may however increase with 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 may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes

Flevox 67 mg spot-on solution for small dogs
Cardboard box containing 1 blister of 1 pipette of 0.67 ml
Cardboard box containing 3 blisters of 1 pipette of 0.67 ml
Cardboard box containing 6 blisters of 1 pipette of 0.67 ml
Cardboard box containing 30 blisters of 1 pipette of 0.67 ml
Cardboard box containing 36 blisters of 1 pipette of 0.67 ml
Cardboard box containing 50 blisters of 1 pipette of 0.67 ml

Flevox 134 mg spot-on solution for medium dogs
Cardboard box containing 1 blister of 1 pipette of 1.34 ml
Cardboard box containing 3 blisters of 1 pipette of 1.34 ml
Cardboard box containing 6 blisters of 1 pipette of 1.34 ml
Cardboard box containing 30 blisters of 1 pipette of 1.34 ml
Cardboard box containing 36 blisters of 1 pipette of 1.34 ml
Cardboard box containing 50 blisters of 1 pipette of 1.34 ml

Flevox 268 mg spot-on solution for large dogs
Cardboard box containing 1 blister of 1 pipette of 2.68 ml
Cardboard box containing 3 blisters of 1 pipette of 2.68 ml
Cardboard box containing 6 blisters of 1 pipette of 2.68 ml
Cardboard box containing 30 blisters of 1 pipette of 2.68 ml
Cardboard box containing 36 blisters of 1 pipette of 2.68 ml
Cardboard box containing 50 blisters of 1 pipette of 2.68 ml

Flevox 402 mg spot-on solution for very large dogs
Cardboard box containing 1 blister of 1 pipette of 4.02 ml
Cardboard box containing 3 blisters of 1 pipette of 4.02 ml
Cardboard box containing 6 blisters of 1 pipette of 4.02 ml
Cardboard box containing 30 blisters of 1 pipette of 4.02 ml
Cardboard box containing 36 blisters of 1 pipette of 4.02 ml
Cardboard box containing 50 blisters of 1 pipette of 4.02 ml

Not all pack sizes may be marketed.

Approved: 07 September 2018