SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flevox 402 mg spot-on solution for very large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pipette of 4.02 ml contains:

Active substance:
Fipronil 402 mg

Excipients:
Butylhydroxyanisole (E320) 1.608 mg
Butylhydroxytoluene (E321) 0.804 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution
Limpid, yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) 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.

ii) 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.

iii) Other precautions

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

4.6 Adverse reactions (frequency and seriousness)

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 as 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).

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For external use only.
Spot-on use.
Animals should be weighed accurately prior to treatment.

Apply topically 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.

Method of Administration:
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 contents 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.

4.10 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides
ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by inhibiting GABA complex, binding to the chloride channel and thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarids.
Fipronil also inhibits glutamate-activated chloride channels (GloCls) which are only found in invertebrates.

5.2 Pharmacokinetic particulars

After a local application of fipronil to the dog, it is slightly absorbed through the skin. Low levels of fipronil may be detected in the plasma, with a very high variability between dogs. After application, there is a good distribution of the chemical in the hair, presenting a good gradient of concentration between the application zone and the peripheral area.
The principal metabolite is the sulfone derivative of fipronil, which also possesses insecticidal and acaricidal properties. The concentrations of fipronil on the hair decrease with time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Povidone (K17)
Diethylene glycol monoethyl ether

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The primary packaging consists of pipettes made of a polyacrylonitrile / polypropylene - cyclic olefin copolymer - polypropylene / polypropylene thermoforming foil sealed with a polyacrilonitrile / aluminium / polyethylene terephthalate lid foil.

Each pipette is included in one individual blister.

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4128

9. DATE OF FIRST AUTHORISATION

3 October 2011

10. DATE OF REVISION OF THE TEXT

September 2018

Approved: 07 September 2018