SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprex XL 412.5 mg spot-on solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One pipette (5.5 ml) contains:

Active substance: Fipronil	412.5 mg
Excipients:	
Butylhydroxytoluene (E321)	16.5 mg
Butylhydroxyanisole (E320)	16.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Light yellow to intensive yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the treatment of fleas (*Ctenocephalides felis*) and ticks (*Rhipicephalus sanguineus, Dermacentor reticulatus*) infestations.
The product shows immediate insecticidal effect and persistent insecticidal activity against new infestations by adult fleas for up to 8 weeks.
The product has a persistent acaricidal efficacy against *Rhipicephalus sanguineus* and *Dermacentor reticulatus* for up to 4 weeks. If ticks of these species are present when the product is applied, all ticks will not be killed within the first 48 hours but they may be killed within a week.
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.

4.3 Contraindications

The product should not be used on puppies less than 2 months old and/or weighing less than 40 kg.
Do not use on sick (systemic disease, fever etc.) or convalescent animals.
Do not use in rabbits, as adverse drug reactions and even death could occur.
This veterinary medicinal product has been developed specifically for dogs. Do not use on cats as this could lead to overdosing.
Do not use on animals with hypersensitivity to active substance or any other excipients.
Do not apply on damaged skin of the animal.

4.4 Special warnings for each target species

Prevent the animals from licking the site of application a few hours after treatment.
All cats and dogs in the household should undergo the treatment.

No data on the effect of bathing/shampooing on the efficacy of the product in dogs are available. Therefore, bathing/immersion in water within 2 days of application and more frequent bathing than once a week should be avoided.
There may be an attachment of some ticks but ticks will be killed in the first 24-48 hours after attachment. This will be usually prior to full engorgement and therefore minimising but not excluding the risk of transmission of diseases.
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 used as part of a strategy for the treatment of flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

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

4.5 Special precautions for use

Special precautions for use in animals
For external use only.

It is important to make sure that the product is applied to an area where the animal cannot lick it off. Do not allow recently treated animals to lick each other.

Avoid contact with the animal's eyes. Should the veterinary medicinal product come into contact with the eyes, rinse thoroughly at once with water.
Animals should be weighed accurately prior to treatment.
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 (see section 6.1.) should avoid contact with the veterinary medicinal product.
Avoid contents coming into contact with the skin. If this occurs, wash hands with soap and water.
This product can cause mucous membrane and eye irritation. Contact of the product with mouth and eyes should be avoided. In the case of accidental eye contact, immediately and thoroughly rinse the eyes carefully with plain water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
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.
Avoid contact with treated animals until the application site is dry. 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
Product may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application (See section 6.6).
The product may have adverse effects on painted, varnished or other household surfaces or furnishing.

4.6 Adverse reactions (frequency and seriousness)

If the animal licks the application site, hypersalivation, vomiting, or neurological symptoms (hypersensitivity or lethargy) may occur.
Hair coat discolouration, local hair loss, irritation, itching or oily appearance may occur at the application site.

4.7 Use during pregnancy and lactation

Laboratory studies in animals have not produced any evidence of a teratogenic or embryotoxic effect.
No studies have been carried out on pregnant or lactating dogs using this veterinary medicinal product. Therefore its use during pregnancy and lactation should only be after a relevant benefit-risk analysis made by the treating veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Application:
Application– spot-on use.
One pipette (5.5 ml) containing 412.5 mg of fipronil per dog weighing 40-55 kg.
Animals should be weighed prior to treatment.

Method of administration:

Open the pipette by tearing off the tip. Part the fur between the shoulder blades and apply the pipette content onto the animal's skin.
If necessary, administer the product to more than one spot between the shoulder blades to minimise the chances of run-off and to ensure the whole dose is administered.
In the absence of safety studies, the minimum treatment interval is 4 weeks.
The current epidemiological situation in the area concerned should always be taken into account.

Following the manufacturer's instructions and warnings will reduce to a minimum the possibility of occurrence of adverse reactions.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The risk of adverse reactions (see section 4.6) may be greater in the case of overdose. Overdose may cause muscular contractions and convulsions. In a few cases, agitation, sleepiness and hypersensitivity to noise and light occurred. Also, transient vertigo, excessive salivation and vomiting were observed. At the site of product application, transient reddening or irritation of the skin may occur. To reduce their intensity, symptomatic treatment may be used.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for topical use
ATC vet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil, the active substance of the product, blocks the flow of chlorides to invertebrate nerve cells which is regulated by GABA receptors (gamma-aminobutyric acid) - the main inhibitory neurotransmitters in central nervous system. As a result of fipronil's activity, the flow of chloride ions through the chloride channels in blocked. Blocking of the inhibition processes leads to the occurrence of uncontrolled excitation which causes death of insects and acarids.

5.2 Pharmacokinetic particulars

A hydrophobic substance, Fipronil is dissolved in the lipid layer which covers the skin. Thanks to translocation in the lipid layer, Fipronil is spread evenly over the entire skin surface, penetrates into sebaceous glands from where it is gradually secreted onto the surface of epidermis.
The veterinary medicinal product distributes itself within 48 hours over the entire skin of the animal.
The absorption of fipronil is negligible in dogs following topical application.
The concentration of fipronil on the fur decreases over time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life for the veterinary medicinal product, packed in immediate packages, is 3 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4. Special precautions for storage

Store below 25^{o}C. Do not refrigerate.

6.5 Nature and composition of immediate packaging

LDPE/HDPE pipette 5.5 ml with HDPE tip, contained in a carton box.
LDPE/HDPE pipette 5.5 ml with HDPE tip, 3 pipettes contained in a carton box.
LDPE/HDPE pipette 5.5 ml with HDPE tip, contained in a carton box, with 12 carton boxes contained in one common carton box.
Available packages:
1x5.5ml, 3x5.5ml, 12x5.5ml.
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 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.

7. MARKETING AUTHORISATION HOLDER

Vet-Agro Trading Sp. Z o.o.
Melgiewska str. 18
20-234 Lublin
Poland

8. MARKETING AUTHORISATION NUMBER

Vm 41715/4004

9. DATE OF FIRST AUTHORISATION

16 August 2016

10. DATE OF REVISION OF THE TEXT

March 2017

Approved: 09 March 2017