PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprex XL 412.5 mg spot-on solution for dogs

Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One pipette (5.5 ml) contains:
Active substance: Fipronil 412.5 mg
Excipients:
Butylhydroxytoluene (E 321) 16.5 mg
Butylhydroxyanisole (E 320) 16.5 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 5.5 ml
3 x 5.5 ml
12 x 5.5 ml

5. TARGET SPECIES

Dogs.

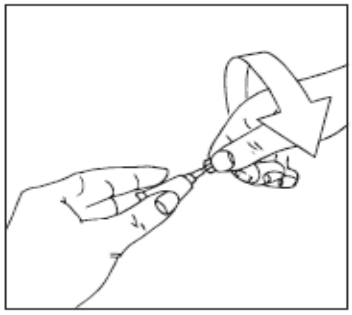
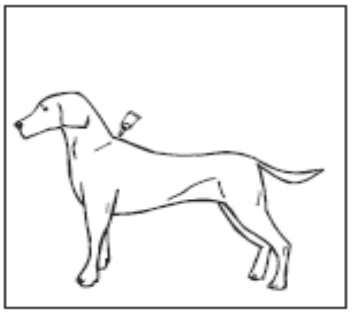
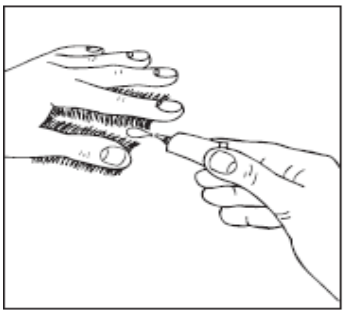
6. INDICATIONS

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.

Read the package leaflet before use

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
Application– spot-on use.
One pipette (5.5ml) containing 412.5 mg of fipronil per dog weighing 40 - 55 kg.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: {month/year}
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

For animal treatment only.
To be supplied only on veterinary prescription. (According to Marketing Authorisation)

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

VET-AGRO TRADING Sp. z o.o.
Mełgiewska str. 18
20-234 Lublin
Poland

16. MARKETING AUTHORISATION NUMBER

Vm 41715/4004

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprex XL 412.5 mg spot-on solution for dogs

Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE

Fipronil 412.5 mg/pipette

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

5.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET
Fiprex XL 412.5 mg spot-on solution for 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 :
VET-AGRO TRADING Sp. z o.o.
Mełgiewska str. 18
20-234 Lublin
Poland

Manufacturer for the batch release:
Przedsiębiorstwo Wielobranżowe Vet-Agro Sp.z o.o.
Gliniana str. 32, 20-616 Lublin
Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprex XL 412.5 mg spot-on solution for dogs

Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One (5.5 ml) pipette contains:
Active substances: Fipronil 412.5 mg
Excipients:
Butylhydroxytoluene (E321) 16.5 mg
Butylhydroxyanisole (E320) 16.5 mg
Light yellow to intensive yellow solution.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

The product should not be used on dogs 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 on 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 the active substance or any other excipients.
Do not apply on damaged skin of the animal.

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Method of 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 tube by tearing off the tip. Part the fur between the shoulder blades and apply the tube 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 application 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.

9. ADVICE ON CORRECT ADMINISTRATION

It is important to make sure that the product is applied to an area where the animal cannot lick it off.
Animals should be weighed before treatment.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25°C. Do not refrigerate.
Do not use after the expiry date which is stated on the pipette and carton after EXP.
The expiry date refers to the last date of that month.
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Prevent the animals from licking the site of application a few hours after treatment.
Do not allow recently treated animals to lick each other.
For external use only.

Avoid contact with the animal's eyes. Should the veterinary medicinal product come into contact with the eyes, rinse thoroughly at once with water.
Do not apply the product on wounds or damaged skin.

All cats and dogs in the household should undergo the treatment.
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.

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 (disease transmitted by ticks).

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.

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.

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 the treated animals 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
Product may adversely affect aquatic organisms.
Dogs should not be allowed to swim in watercourses for 2 days after application.
The product may have adverse effects on painted, varnished or other household surfaces or furnishing.

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

15. OTHER INFORMATION

Overdose
The risk of adverse reactions 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.

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.

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, with12 carton boxes contained in one common carton box.
Not all pack sizes may be marketed.
Available pack sizes:
1 x 5.5 ml, 3 x 5.5 ml, 12 x 5.5 ml

Approved: 09 March 2017