ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprex M 150 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette of 2 ml contains:

Active substances:

Fipronil 150 mg

3. PACKAGE SIZE

1 x 2 ml
3 x 2 ml
12 x 2 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

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

6. ROUTES OF ADMINISTRATION

Spot-on use.

One pipette of 2 ml containing 150 mg of fipronil per dog weighing 10-20 kg.

[Three pictograms:
1- pictogram showing the way of broaching the pipette with an arrow indicating twisting
2- pictogram showing a standing dog and the pipette above the neck - the correct place to administer the product
3- pictogram showing a hand parting the fur and the pipette above this place - the correct way to administer the product]

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Do not refrigerate.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vet-Agro Trading Sp. z o.o.

14. MARKETING AUTHORISATION NUMBERS

Vm 41715/3001

15. BATCH NUMBER

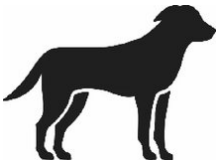
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprex M



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 150 mg/pipette

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fiprex M 150 mg spot-on solution for dogs

2. Composition

Each pipette of 2 ml contains:

Active substances:

Fipronil 150 mg

Excipients:
Butylhydroxytoluene (E321) 6.0 mg
Butylhydroxyanisole (E320) 6.0 mg

Light yellow to intensive yellow solution.

3. Target species

Dogs

4. Indications for use

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

Do not use in puppies less than 2 months old and/or weighing less than 10 kg.
Do not use in 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 in cats as this could lead to overdosing.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not apply on damaged skin of the animal.

6. Special warnings

Special warnings:
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 veterinary medicinal 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.

Special precautions for safe use in the target species:
For external use only.

It is important to make sure that the veterinary medicinal 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. If 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 veterinary medicinal 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 to any of the excipients should avoid contact with the veterinary medicinal product.
Avoid contents coming into contact with the skin. In case of accidental skin contact, wash hands with soap and water.
This veterinary medicinal product can cause mucous membrane and eye irritation.
Contact of the veterinary medicinal product with mouth and eyes should be avoided.
In 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 veterinary medicinal product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the veterinary medicinal product. In case of accidental ingestion of veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician.
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.

Special precautions for the protection of the environment:
Veterinary medicinal product may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Other precautions:
The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishing.

Pregnancy and lactation:
Laboratory studies in animals have not produced any evidence of teratogenic or embryotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy or lactation in the target species.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
No data available.

Overdose:
The risk of adverse events (see section “Adverse events”) 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 veterinary medicinal product application, transient reddening or irritation of the skin may occur. To reduce their intensity, symptomatic treatment may be used.

Special restrictions for use and special conditions for use:
Not applicable.

7. Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data)	Application site hair coat discolouration, Application site hair loss, Application site itching, Application site irritation, Application site greasy fur

	Hypersalivation[1], Vomiting[1] Neurological disorders (Lethargy, Hypersensitivity)[1]

[1] May occur if the animal licks the application site.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Spot-on use.

One pipette of 2 ml containing 150 mg of fipronil per dog weighing 10-20 kg.

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 veterinary medicinal 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.

9. Advice on correct administration

Animals should be weighed prior to treatment. To ensure a correct dosage, body weight should be determined as accurately as possible.

It is important to make sure that the veterinary medicinal 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 veterinary medicinal 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.

10. Withdrawal periods

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 this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 41715/3001

Package size:
Carton box with 1 pipette.
Carton box with 3 pipettes.
Carton box containing 12 carton boxes with 1 pipette.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Vet-Agro Trading Sp. Z o.o.
Melgiewska str. 18
20-234 Lublin
Poland

Manufacturer responsible for batch release:
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin,
Poland

Contact details to report suspected adverse reactions:

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Gavin Hall
Approved: 09 December 2025