<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPROSPOT 50 mg Spot-on solution for cats
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each pipette contains fipronil 50 mg

Excipients:

Butylhydroxyanisole (E 320)	0.10 mg
Butylhydroxytoluene (E 321)	0.05 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

3 pipettes
6 pipettes
12 pipettes
24 pipettes
60 pipettes
120 pipettes

5. TARGET SPECIES

For cats

6. INDICATION(S)

Against fleas and ticks.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

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

Disposal: read 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Distributed by:
to be determined nationally

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch number

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPROSPOT 50 mg Spot-on solution for cats
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

LOGO (of IDT)
IDT Biologika GmbH

or

Distributed by:
LOGO (of distributor)
Name of the distributor (to be determined nationally)

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON PIPETTE

Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPROSPOT
50 mg Fipronil

2. EXPIRY DATE

EXP

3. BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

FIPROSPOT 50 mg Spot-on solution for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Manufacturer responsible for batch release
Klocke Verpackungs-Service GmbH
Max-Becker-Str. 6
76356 Weingarten
Germany

Distributed by:
to be determined nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPROSPOT 50 mg Spot-on solution for cats
Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 0.5 ml pipette contains

Active substance:

Fipronil	50.00 mg

Excipients

Butylhydroxyanisole (E 320)	0.10 mg
Butylhydroxytoluene (E 321)	0.05 mg

Clear, colourless to yellowish solution.

4. INDICATIONS

For the treatment of cats against flea infestations (*Ctenocephalides* spp.).
Insecticidal efficacy against new infestation with fleas persists for up to 4 weeks.

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.

Although the product has not demonstrated an immediate acaricidal effect, acaricidal efficacy for up to 1 week against the tick *Ixodes ricinus* has been shown. If ticks of *Ixodes ricinus* 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 kittens less than 8 weeks old and/or weighing less than 1 kg in the absence of available data.
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.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier substance.
Among the very rare suspected adverse reactions, transient cutaneous reactions at the application site (scaling, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use.
Very rare, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs) or vomiting have been 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

Cat

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

Method of application and posology:
Only by topical application to the skin. External use only.

1 pipette of 0.5 ml is sufficient for the treatment of a cat corresponding to a recommended minimum dose of 5 mg fipronil/kg body weight.

The minimum interval between two treatments should be not less than 4 weeks.

9. ADVICE ON CORRECT APPLICATION

Disconnect one of the blisters from the blister card. This helps to avoid accidental opening of the adjacent blister package in order to protect the still unopened pipettes from exposure to humidity. Open the blister with scissors. To avoid damaging of the pipette cut along the line marked with the scissors icon. Carefully peel back the foil from the cut off end and withdraw the pipette.

Hold the pipette upright. Tap lightly to ensure the entire liquid contents are within the main body of the pipette. Bend the upper border strip backwards. Then the pipette can be set aside, if necessary. To open the pipette snap off the top of the pipette along the scored line.

Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its content completely and directly onto the skin in one spot.

Application of the solution near the base of the head minimises the possibility that the animal will lick the solution off. Care should be taken after the application that animals do not mutually lick off the solution.

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.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTION

This veterinary medicinal product does not require any special storage conditions. Store in the original package.

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 label after EXP.

12. SPECIAL WARNINGS

The veterinary medicinal product does not prevent an infestation of the animal by ticks.

For the optimal control of flea problems in households with several animals all dogs and cats should be treated with an authorised insecticide.

Fleas from pets often infest animal's baskets, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestion and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

The influence of bathing/shampooing on the efficacy of this veterinary medicinal product in cats has not been investigated. However, from studies conducted in dogs, shampooing with a medicated shampoo, followed by thorough drying, 1 to 2 hours before treatment application and bathing once weekly over a period of 6 weeks has been shown not to affect the efficacy of this veterinary medicinal product against fleas in dogs. Bathing and intensive wetting of the coat should be avoided for the first 2 days following administration of the product.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patients and to other animals in the household are recommended.

Special precautions for use in animals:

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.

Do not apply the veterinary medicinal product to wounds or skin lesions.

There may be an attachment of some ticks. For this reason transmission of infectious diseases cannot be excluded if conditions are unvavourable.

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 between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Avoid contents coming into contact with the fingers. If this occurs, wash off immediately with soap and water.
Wash hands after use.
Do not smoke, drink or eat during application.
People with a known hypersensitivity to fipronil or other excipients should avoid contact with the veterinary medicinal 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
The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in cats during pregnancy and lactation. Laboratory studies using fipronil have not shown any evidence of teratogenic or foetotoxic effect. Use in pregnancy and lactation only in accordance with the benefit/risk assessment of the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes)

The toxicity of the veterinary medicinal product administered to the skin is very low. The risk of experiencing adverse effects (see section 6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to body weight.

Specific studies investigating the safety of the product following repeated administration or at overdosage have not been conducted due to the known safety profile of the active substance and excipients.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
Fipronil may be harmful to 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

The veterinary medicinal product distributes itself within 24 – 48 hours over the entire skin of the animal.

Package sizes:

A blister card consists of 3 blisters each containing a single pipette.
Packs containing 3, 6, 12, 24, 60 and120 pipettes.
Not all pack sizes may be marketed