SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPROSPOT 268 mg Spot-on solution for large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2.68 ml pipette contains

Active substance:

Fipronil	268.00 mg

Excipients

Butylhydroxyanisole (E 320)	0.536 mg
Butylhydroxytoluene (E 321)	0.268 mg

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Spot-on solution
Clear, colourless to yellowish solution

4. CLINICAL PARTICULARS

4.1 Target species

Dog (20 – 40 kg)

4.2 Indications for use, specifying the target species

For the treatment of dogs against flea infestations (*Ctenocephalides* spp.)
Insecticidal efficacy against new infestation with fleas persists for up to 6 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 does not consistently show an immediate acaricidal efficacy (several ticks may be present after 48 hours), it has a persistent acaricidal efficacy for up to 4 weeks against *Dermacentor variabilis* and up to 3 weeks against *Rhipicephalus sanguineus*.

4.3 Contraindications

Do not use on puppies less than 2 months old and/or weighing less than 2 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.

This veterinary medicinal product has been developed specifically for dogs. Do not use on cats as this could lead to overdosing.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

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

Ticks will usually die within 48 hours of infestation, however attached ticks (both live and killed) may be seen at this time. Some of these will have had a blood meal.

Death normally occurs before the ticks are fully engorged so that the risk of transmission of infectious diseases by ticks is minimised, but cannot be completely ruled out. As soon as the ticks are dead they generally fall off the animal; remaining ticks can be removed with a gentle pull.

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 infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

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. Bathing and intensive wetting of the coat should be avoided for the first 2 days following administration of the veterinary medicinal 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.

4.5 Special precautions for use

Special precautions for use in animals:

This veterinary medicinal product should not be used on dogs weighing less than 20 kg.

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 completely excluded if conditions are unfavourable.

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

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 furnishings.

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 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), vomiting or respiratory signs 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)

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not shown any evidence of teratogenic or foetotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

4.8 Interactions with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

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

Animals should be weighed accurately prior to treatment.

1 pipette of 2.68 ml is sufficient for the treatment of a dog with a body weight of 20 kg up to 40 kg corresponding to a recommended minimum dose of 6.7 mg fipronil/kg body weight.

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

Advice for the safe 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 or two spots.

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.

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

The toxicity of the veterinary medicinal product administered to the skin is very low. The risk of experiencing adverse effects (see section 4.6) 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.

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Ectoparasiticides; Fipronil
ATCvet Code: QP53AX15

5.1 Pharmacodynamic properties:

Fipronil is an insecticide and acaricide belonging to the group of phenylpyrazole. It acts by inhibiting the GABA complex, binding to the chloride channel thereby blocking pre- and post-synaptic transfer of chloride ions across the membrane. This results in uncontrolled activity of the central nervous system and hence to death in insects and acarids.
Fipronil acts as an insecticide against fleas (*Ctenocephalides* spp.) and as an acaricide against ticks (*Rhipicephalus sanguineus* and *Dermacentor variabilis*).
Fleas are killed within 48 hours. Most ticks are killed within 48 hours. Some ticks may still be present after 48 hours.

5.2 Pharmacokinetic particulars

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

Butylhydroxyanisole (E 320)
Butylhydroxytoluene (E 321)
Diethylene glycol monoethyl ether

6.2 Incompatibilities:

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months

6.4 Special precautions for storage

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

Store in the original package.

6.5 Nature and composition of immediate packaging

Pipettes containing an extractable volume of 2.68 ml.

The pipettes are made of:
- bottom foil: polyethylene terephthalate/polypropylene
- lidding foil: polyethylene terephthalate/aluminium

To protect the content of the pipettes from moisture and light the pipettes are individually packed in blister foils made of:
- cold-form foil for blister: polyvinyl chloride/(biaxially) oriented polyamide/aluminium/polyvinyl chloride
- lidding foil for blister: polyethylene terephthalate / aluminium

A blister card consists of 3 blisters, each containing a single pipette.

Packs containing 3, 6, 12, 24, 60 and 120 pipettes.

Not all pack sizes may be marketed.

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

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 be harmful to aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

IDT Biologika GmbH
Am Pharmapark
D-06861 Dessau-Rosslau
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 26750/4001

9. DATE OF FIRST AUTHORISATION

20 January 2011

10. DATE OF REVISION OF THE TEXT

March 2016

Approved: 04 March 2016