Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Parex 67 mg spot-on solution for small dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.67 ml pipette contains

Active substance:

Fipronil	67.00	mg

Excipients

Butylhydroxyanisole (E 320)	0.134	mg
Butylhydroxytoluene (E 321)	0.067	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 (>2 – 10 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.

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

In the absence of available data, the veterinary medicinal product should not be used on puppies less than 2 months old and/or weighing less than 2 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

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.

4.5 Special precautions for use

Special precautions for use in animals:

Animals should be weighed accurately prior to treatment.

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore avoid contact of the product with mouth and eyes.
Should the veterinary medicinal product come into contact with the eyes, rinse thoroughly at once with water. If the eye irritation persists, seek medical help at once and show the package insert or label.
Avoid contact with the skin. Should the product come into contact with the skin, wash with soap and water. Wash hands after use.

Do not eat, drink or smoke during application.

People with known hypersensitivity to fipronil or any of the excipients should avoid contact with this 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 during the early evening. Moreover recently treated animals should not be allowed to sleep with owners, especially children.

Other precautions:
Fipronil is toxic for 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, vanished or other household surfaces or furnishing.

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 rarely, 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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not shown any 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 interactions

None known.

4.9 Amounts to be administered and administration route

Route of application and posology:
Spot-on use. Only by topical application to the skin.

1 pipette of 0.67 ml is sufficient for the treatment of a dog with a body weight of 2 kg up to 10 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.

Method of administration:
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.

4.10 Overdose (symptoms, emergency procedures, 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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 Major 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 0.67 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 precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national 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

CF Pharma Limited
The Racecourse
Danesfort
Kilkenny
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10515/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 November 2013
Date of last renewal: 24 November 2018

10 DATE OF REVISION OF THE TEXT

January 2021