

Parex 50 mg Spot-on Solution for Cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORITY-HOLDER AND OF THE MANUFACTURING AUTHORITY-DIFFERENT

Marketing authorisation holder:

CF Pharma Ltd
The Racecourse,
Danesfort
Co. Kilkenny
Ireland

Manufacturer for the batch release:

Klocke Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Germany

Distributed by:

Uniphar Group
4045 Kingswood Road
Citywest Business Park,
Co. Dublin
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parex 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: 50.00 mg
Fipronil

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.).

The product has a persistent insecticidal efficacy for up to 4 weeks against fleas.

Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy for up to 1 week against the tick Ixodes ricinus. If ticks of this species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they will be killed within a week.

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 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.

Do not use on animals with hypersensitivity to the active substance or any other ingredients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation (a lot of saliva in the cat's mouth) may be observed due mainly to the nature of the ingredients.

Among the extremely rare suspected adverse reactions, temporary skin reactions on the application site (skin discoloration, local hair loss, pruritus (hives, rash), erythema (redness)) and general pruritus (hives, rash) or hair loss have been reported after use..

Exceptionally, hypersalivation, reversible neurological symptoms (hyperaesthesia(oversensitivity), depression, nervous symptoms) or vomiting have been observed after use.

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.

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 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 after the expiry date which is stated on the blister and carton after EXP.

12. SPECIAL WARNINGS

The product does not prevent ticks from attaching to the animals.

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.

The influence of bathing/shampooing on the efficacy of this 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 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.

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 product come into contact with the eyes, rinse thoroughly at once with water.

Do not apply the product to wounds or damaged skin.

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

Specific studies investigating the safety of the product following repeated administration or at overdose 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:

This product can cause mucous and eye irritation. Therefore avoid contact of the product with mouth and eyes.

Should the 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.

Animals or people with known hypersensitivity to fipronil or one of its ingredients should avoid contact with the 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

The product may have adverse effects on painted, vanished or

other household surfaces or furnishing.

Use during pregnancy and lactation

Laboratory studies using fipronil have not shown any teratogenic or embryotoxic effect. No studies have been carried out on pregnant or lactating cats using this product. Therefore its use during pregnancy and lactation should only be after a relevant benefit-risk analysis made by the treating veterinarian.

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

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. 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:

November 2013

15. OTHER INFORMATION

The 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 and 120 pipettes. Not all pack sizes may be marketed.

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