

PRODUCT INFORMATION LEAFLET

pareX

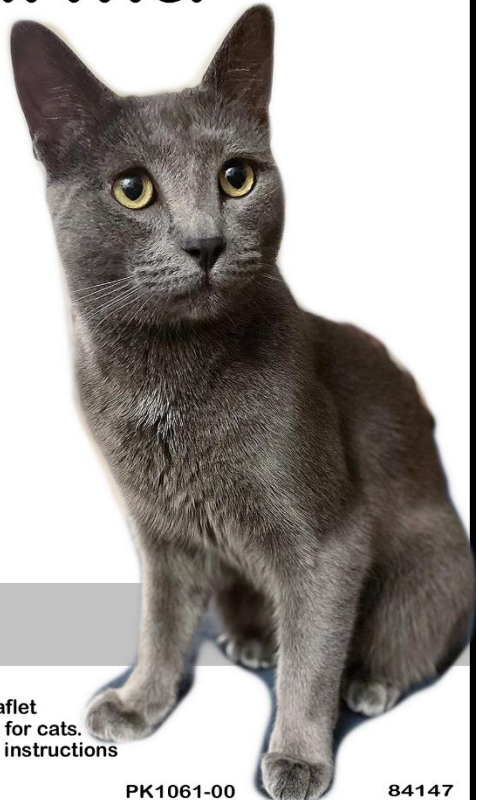
50 mg

SPOT-ON SOLUTION FOR CATS

Cfpharma+

for
ticks
& fleas

VPA 10515/001/001
LM-Licensed Merchant
Cfpharma+



NOTE: Please keep this information leaflet
with your pareX 50mg spot on solution for cats.
Read it carefully. It contains important instructions
for using this product.

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INFORMATION FOR USER

Parex 50 mg

Spot-On Solution for Cats

NOTE: Read all the information on this leaflet carefully before using this product. Do not destroy or throw away this leaflet. You may need to refer to it again. If there is anything in this leaflet that you do not understand please consult your veterinary doctor.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parex 50 mg spot-on solution for cats

Fipronil

2. WHAT PAREX 50 MG SPOT-ON SOLUTION IS USED FOR

This product is for the treatment of flea infestations in cats.

It is only **suitable for use only on cats**.

3. ACTIVE SUBSTANCE(S) AND EXCIPIENTS

Each 0.5 ml pipette contains

Active substance

Fipronil 50.00 mg

Excipients

Butylhydroxyanisole (E320) 0.10 mg

Butylhydroxytoluene (E321) 0.05 mg

Appearance:

Clear, colourless to yellowish solution

4. PACKAGING INFORMATION

Each card consists of 3 blisters each containing a single pipette.

Packs containing 3,6,12, 24, 60 and 120 pipettes are produced though not all pack sizes maybe available on the market.

5. INDICATIONS

For the treatment of flea (ctenoccephalides spp) infestations in cats.

This product has a persistent insecticidal efficacy against fleas of up to 4 weeks.

Although no immediate killing effect against ticks has been demonstrated,

the product has shown an acaricidal efficacy against the tick *Ixodes ricinus* for up to 1 week. If ticks of this species are present on the cat when the product is applied, all the ticks will be killed between 48 hours and one week.



Figure 1: Parex 50mg is effective against ticks and flea infestations amongst cats

6. CONTRA-INDICATIONS

This product should not be used on kittens less than 8 weeks old and or weighing less than 1kg.

Do not use on sick animals.

Consult your doctor if your cat is sick.

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

Must not be used on rabbits. Adverse reaction to the drug can cause death.

7. ADVERSE REACTIONS

If your cat licks this product, it may experience a brief period of hypersalivation (secreting a lot of saliva in its mouth). This is due mainly to the ingredients of this product.

In extremely rare adverse reactions, cats have reportedly experienced temporary skin reactions on the application site including skin discoloration, local hair loss, pruritus (hives, rash) and erythema (redness).

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

If you notice any serious reactions other than those mentioned in this leaflet, please consult your veterinary doctor.

8. SPECIAL WARNINGS

This 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. Please note that this product can only be used on cats.

Fleas from pets often infect the animal's basket, beddings, and regular resting areas such as carpets and soft furnishings. If there is a serious flea infestation, these areas should be treated with appropriate insecticides.

Please use suitable insecticide and vacuum clean the carpets regularly.

The impact of bathing/shampooing cats on the efficacy of this product has not been investigated.

However, studies conducted on dogs have shown that shampooing with a medicated shampoo, followed by thorough drying, 1 to 2 hours before application of this flea treatment product does not have any impact on the effectiveness of this product.

Bathing once weekly over a period of 6 weeks has also proved not to impinge on the efficacy of this product against fleas in dogs.

However, bathing, and intensive wetting of the coat should be avoided for the first two days following administration of this product.



- **Special precaution for use in animals:**

- Apply this product to a part of the cat's body where the animal cannot lick it off. **See Figure 2 on Page 6.**
- Do not allow recently treated animals to lick each other.
- Do not apply this product to the cat's eye.
- Should the product enter the cat's eyes, rinse thoroughly with water.
- Do not apply the product to wounds or damaged skin.
- This product does not prevent the transmission of infectious diseases.
- Studies have not been carried to investigate the safety of this product if an overdose is applied.

- **Caution During Application**

- Do not touch your mouth and eyes while using this product as it may cause irritation.
- Should the product come into your eyes, rinse thoroughly at once with plenty of water.
- If irritation to the eyes persists, seek immediate medical help by calling **112** or **999**, and show the package label or this leaflet to the health worker.
- Do not apply this product to your skin.
- Should the product get on your skin, wash it off with plenty of soap and water.
- Wash your hands thoroughly after using this product.
- Do not eat or drink anything while using this product.
- Avoid contact with the product if you are hypersensitive to Fipronil or any of the ingredients in this product. **See Section 3 on Page 3 for ingredients.**
- Should not be used on animals known to be hypersensitivity to Fipronil or any of its ingredients
- Animals that have been treated with this product must not be handled until after site where the product was application is dry.
- Children must not be allowed to play with animals that have been treated with the product until the application site is verifiably dry.
- It is recommended that animals be treated with the product during the early evening to minimise chances of contact with humans.
- Animals that have been treated with Parex 50 mg spot-on solution for cats must not sleep with humans.



- **Other precautions**

Parex 50 mg spot-on solution for cats may have adverse effects on painted, vanished, or other household surfaces or furnishings.

- **Use During Pregnancy and Lactation**

- Laboratory studies have not shown any teratogenic or embryotoxic effect from fipronil.
- No studies have been carried out on pregnant or lactating cats using this product.
- Use of this product during pregnancy and lactation should only be considered after a risk benefit analysis conducted by a veterinarian.
- The toxicity of the product administered to the skin is very low.

- The risk of experiencing adverse effects (see adverse reactions) may however increase with overdosing.
- Animals should always be treated with the correct pipette size according to advice by a veterinarian.

9. DIRECTIONS ON CORRECT USE

1. Remove one blister from the pack at a time.
2. Be careful. Do not damage or open the adjacent blisters on the pack. This is to protect the unopened pipettes from exposure to humidity which might affect effectiveness of product.
3. Open the blister with a pair of scissors by cutting along the line marked with the scissor's icon.
4. Peel back the foil from the cut off end and carefully remove the pipette.
5. Hold the pipette upright. Tap it lightly to ensure the entire liquid contents are within the main body of the pipette.
6. Bend the upper border strip backwards.
7. Snap off the top of the pipette along the dotted line to open the pipette.
8. Hold your cat firmly then part the fur coat between its shoulder blades until the skin of the animal is visible. **Refer to Figure 2.**
9. Place the tip of the open pipette on the skin of the cat and squeeze the pipette several times to empty its contents completely and directly onto the skin of the cat in one spot.

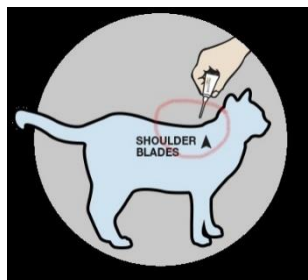


Figure 2: The spot on a cat where the treatment solution should be applied.

NOTE: Application of the solution near the base of the head minimises the possibility that the cat will lick the solution.

- Make sure that after application the animals do not mutually lick off the solution.
- Avoid excessive wetting of the hair with the solution because this will cause a sticky appearance of hairs at the treatment spot.
- Should there be a sticky appearance at the treatment spot, do not worry as this should disappear within 24 hours.

10. DOSAGE

- To be applied to the skin of the cat.
- One pipette of 0.5 ml is sufficient for the treatment of one cat.
- Treatment should not be repeated until after 4 weeks.
- If you think your cat needs to be retreated please consult your veterinary doctor first.

11. OTHER INFORMATION

The product distributes itself within over the entire skin of the animal between 24-48 hours.

12. WITHDRAWAL PERIOD

Not applicable

13. STORAGE

- Store in original package.
- Keep out of sight and reach of children.
- Do not use the product after its expiry date.
- The expiry date is printed on the blister packaging

14. SAFE DISPOSAL

- Fipronil, the active substance in this product may be harmful to aquatic organism and should not be disposed of in domestic waste.
- Do not discard any unused pipettes or the empty container in ponds, waterways, or ditches.
- Please enquire from your veterinary doctor on how to safely discard any unused product and or empty container or return it to the shop where you purchased it for safe disposal.



15. DATE ON WHICH THIS LEAFLET WAS LAST APPROVED

November 2013

16. CONTACTS

- **Market Authorisation Holder:**
CF Pharma Ltd
The Racecourse,
Danesfort,
Co. Kilkenny, Ireland
<https://cfpharma.ie/>
- **Manufacturer for Batch Release:**
Klocke Verpackungs-Service GmbH
Max-Becker-Str. 6
D-76356 Weingarten
Germany
<https://www.klocke.com/>

- **Distributed by:**
Uniphar Group
4045 Kingswood Road
Citywest Business Park
Co. Dublin, Ireland
<https://www.uniphar.ie/>

STATUTORY RIGHTS: If you are not entirely satisfied with this product please return it to the store where you purchased it and we shall be pleased to replace it or refund it.