

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pets with Wilko Flea Drops 50 mg Spot-on Solution for Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: 50mg Fipronil

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette of 0.5 ml
2 pipettes of 0.5 ml
3 pipettes of 0.5 ml
4 pipettes of 0.5 ml
5 pipettes of 0.5 ml
6 pipettes of 0.5 ml

5. TARGET SPECIES

Cats over 1kg

6. INDICATION(S)

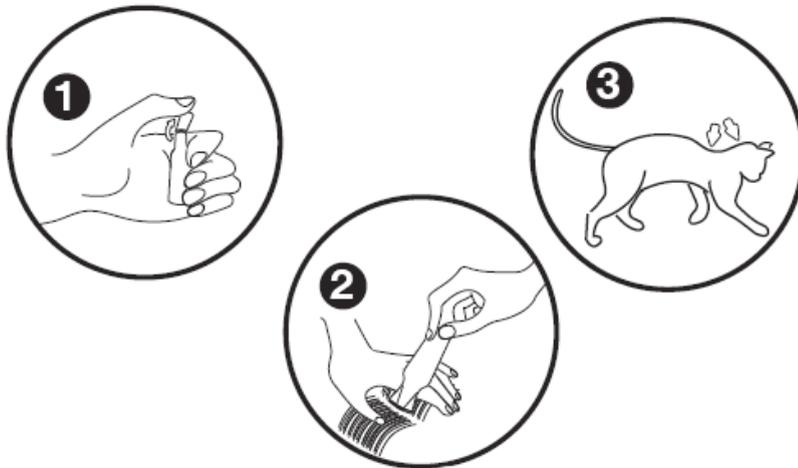
Treatment of flea. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides spp.*).

Treatment of tick (*Dermacentor reticulatus*) infestations. Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Apply one pipette per cat

Please read package leaflet before use for full instructions, including user warnings.



1. Remove the pipette from the blister packaging. Hold the pipette in an upright position and snap-off the top section of the cap, thereby opening the pipette.
2. Part the pet's coat until the skin is visible. Place the tip of the tube directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the cat's back. The first application point is at the base of the head and the second application point is between the shoulder blades. Squeeze the tube several times to ensure dosing is complete. Avoid applying the solution onto the fur and do not rub into the skin.
3. Application of the solution as directed minimises the possibility that the animal will lick the solution off. Do not allow pets to lick each other after treatment.

The minimum interval between two treatments is 4 weeks.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use on cats that are less than 2 months old and/or weight less than 1kg.
Do not use on sick or convalescent animals.
Do not use on rabbits as adverse drug reactions and even death could occur.
Do not use on animals with known hypersensitivity to the active substance or to any of the other ingredients.

Read the enclosed package leaflet before use for full instructions and all warnings. The user safety warnings can also be found on the inner part of the carton box and should be read before each use.

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately.

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.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

People with a known hypersensitivity (allergy) to fipronil or any of the other 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 should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.

10. EXPIRY DATE

EXP: end {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Store in a dry place.

Store in the original package.

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

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of empty packaging and any remaining product in the household refuse.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

For external use 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

Pets Choice Limited
Brentwood House
Lower Philips Road
Whitebirk Industrial Estate
Blackburn
Lancashire
BB1 5UD
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 52797/4017

17. MANUFACTURER'S BATCH NUMBER

Batch no: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC BLISTER WITH FOIL SEAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pets with Wilko Flea Drops 50 mg Spot-on Solution for Cats

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pets Choice Limited

3. EXPIRY DATE

EXP: end {month/year}

4. BATCH NUMBER

Batch No. {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pets with Wilko Flea Drops 50 mg Spot-on Solution for Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD

N/A – companion animal target species

6. BATCH NUMBER

Batch no: {number}

7. EXPIRY DATE

EXP: end {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Pets with Wilko Flea Drops 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:

Pets Choice Limited
Brentwood House
Lower Philips Road
Whitebirk Industrial Estate
Blackburn
Lancashire
BB1 5UD
United Kingdom

Manufacturer responsible for batch release:

Pets Choice Ltd
8 Wemberham Lane
Yatton
North Somerset
BS49 4BS
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pets with Wilko Flea Drops 50 mg Spot-on Solution for Cats

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

One 0.50 ml pipette contains:

Active substance:

Fipronil 50 mg

Excipients:

Butylhydroxyanisole E320 0.1 mg

Butylhydroxytoluene E321 0.05 mg

Clear, pale amber solution

4. INDICATION(S)

Treatment of flea (*Ctenocephalides spp.*) infestations.

The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides spp.*).

Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. 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

Do not use on kittens less than 2 months old and/or weighing less than 1 kg.
Do not use on sick (systemic diseases, fever...) or convalescent animals.
Do not use in rabbits, as adverse drug reactions and even death could occur.
Do not use on animals with known hypersensitivity to the active substance or to any of excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

Among the extremely rare suspected adverse reactions, transient cutaneous reactions on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms 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)

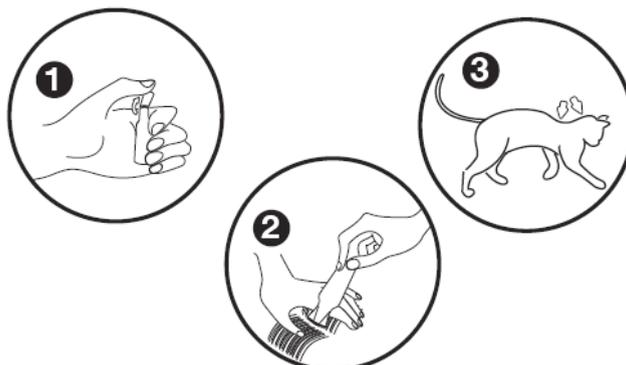
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cat.

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

External use only. Administer by topical application to the skin 1 pipette per animal.



Remove the pipette from the blister packaging. Hold the pipette in an upright position and snap off the top section of the cap, thereby opening the pipette.

Part the pet's coat until the skin is visible. Place the tip of the tube directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the cat's back. The first application point is at the base of the head and the second application point is between the shoulder blades. Squeeze the pipette several times to ensure dosing is complete. Avoid applying the solution onto the fur and do not rub into the skin.

9. ADVICE ON CORRECT ADMINISTRATION

Application of the solution as directed minimises the possibility that the animal will lick the solution off. Do not allow pets to lick each other after treatment.

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 usually disappear within 24-48 hours post application. Crystals may be seen on the hair and slight scaling may occur within 24-48 hours after application.

Treatment schedule:

For optimal control of flea infestation the treatment schedule can be based on the local epidemiological situation.

The minimum interval between two treatments is 4 weeks

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in a dry place.

Store in the original package.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Fleas from pets often infest the animal's basket, 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.

Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Special precautions for use

i) Special precautions for use in animals

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

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

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately. 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.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use.

People with a known hypersensitivity (allergy) to fipronil or any of the other 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 should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.

iii) Other precautions

The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

iv) Use during pregnancy and lactation

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

v) Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse effects were observed in a target animal safety study in 8 week-old kittens weighing about 1 kg treated with 5 times the therapeutic dose once a month for 3 consecutive months. The risk of experiencing adverse effects may increase in cases of over-dose.

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

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Blister cards or boxes of 1, 2, 3, 4, 5 or 6 pipettes.
Not all pack sizes may be marketed.

MARKETING AUTHORISATION NUMBER

Vm 52797/4017

For animal treatment only

Approved 30 August 2022

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.