

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Pets with Wilko Flea Drops 268 mg Spot-on Solution for Large Dogs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Contains: 268 mg Fipronil

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

1 pipette of 2.68 ml  
2 pipettes of 2.68 ml  
3 pipettes of 2.68 ml  
4 pipettes of 2.68 ml  
5 pipettes of 2.68 ml  
6 pipettes of 2.68 ml

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

Large Dogs 20-40 kg

For the treatment of flea (*Ctenocephalides spp.*) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

Pets with Wilko Flea Drops 268 mg Spot-on Solution for Large Dogs has a persistent insecticidal efficacy for up to 8 weeks against fleas (*Ctenocephalides spp.*) and a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus* and *Dermacentor reticulatus*).

If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

Animals should be weighed accurately prior to treatment.

One pipette per dog of 20 – 40kg.

For dogs over 60 kg, use two pipettes of 2.68 ml.

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

Do not use on rabbits!



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 your dog's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the dog's back, preferably at the base of the head and 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.
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.

## 8. WITHDRAWAL PERIOD

## 9. SPECIAL WARNING(S), IF NECESSARY

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.  
Do not use on dogs less than 2 months old and/or weighing less than 20 kg.  
Do not use on sick or convalescent animals.  
Do not use on rabbits, as adverse reactions and even death could occur.  
This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.  
Do not use on animals with known hypersensitivity to the active substance or to any of the excipients.

#### **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.

#### **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 52797/4016

**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 268 mg Spot-on Solution for Large Dogs

**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 268 mg Spot-on Solution for Large Dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

268 mg

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

2.68 ml

**4. ROUTE(S) OF ADMINISTRATION**

Spot on

**5. WITHDRAWAL PERIOD**

**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 Spot-on Solution for Small, Medium and Large Dogs

#### 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  
Somerset  
BS49 4BS  
United Kingdom

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pets with Wilko Flea Drops 67 mg Spot-on Solution for Small Dogs  
Pets with Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs  
Pets with Wilko Flea Drops 268 mg Spot-on Solution for Large Dogs

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

Dog	Weight (kg)	Unit dose	Fipronil	Excipients: Butylhydroxanisole	Excipients: Butylhydroxytoluene
Pets with Wilko Flea Drops 67 mg Spot-on Solution for Small Dogs	2-10	0.67 ml	67 mg	0.134 mg/pipette	0.067 mg/ pipette
Pets with Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs	10-20	1.34 ml	134 mg	0.268 mg/ pipette	0.134 mg/ pipette
Pets with Wilko Flea Drops 268 mg Spot-on Solution for	20-40	2.68 ml	268 mg	0.536 mg/ pipette	0.268 mg/ pipette



Large Dogs					
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Clear, pale amber solution

#### 4. INDICATION(S)

For the treatment of flea (*Ctenocephalides spp.*) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

Pets with Wilko Flea Drops Spot on Solution has a persistent insecticidal efficacy for up to 8 weeks against fleas (*Ctenocephalides spp.*) and a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus* and *Dermacentor reticulatus*).

If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

#### 5. CONTRAINDICATIONS

Do not use on puppies less than 2 months old.

Weigh the puppy first and ensure that the correct product is used based on the weight of the puppy.

This product is not suitable for dogs weighing less than 2 kg.

Pets with Wilko Flea Drops 67 mg Spot-on Solution for Small Dogs is for dogs weighing between 2 and 10 kg.

Pets with Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs is for dogs weighing between 10 and 20 kg.

Pets with Wilko Flea Drops 268 mg Spot-on Solution for Large Dogs is for dogs weighing between 20 and 40 kg.

Do not use on sick (e.g. systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Do not use on animals with known hypersensitivity to the active substance or to any of the 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)

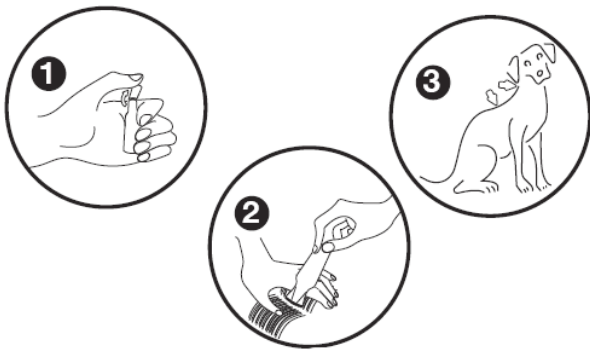
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dog.

## 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, or if over 60kg, 2 pipettes of 2.68ml.



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 your dog's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the dog's back, preferably at the base of the head and 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 and/or tick 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 WARNING(S)**

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

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle twist.

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.

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

When treating infestations, all in-contact dogs should be treated with an appropriate product at the same time.

Special precautions for use

### **i) Special precautions for use in animals**

Animals should be weighed accurately prior to treatment.

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

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.

Do not allow pets to lick each other after treatment

Do not apply the product on wounds or damaged skin.

**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) Environmental warning**

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

**iv) Other precautions**

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

**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 bitches. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

**Interaction with other medicinal products and other forms of interaction**

None known.

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

No adverse effects were observed in target animal safety studies in 2 month-old puppies, growing dogs and dogs weighing about 2 kg treated with 5 times the therapeutic dose once a month for 3 consecutive months. The risk of adverse effects (see section 6) may increase in cases of overdose.

**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.  
For animal treatment only

Vm 52797/4016

Approved 30 August 2022

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