LABELLING AND PACKAGE LEAFLET

# A. LABELLING

# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

# CARTON BOX/BLISTER CARD

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

Bob Martin Clear Spot-on Solution 50 mg for Cats Fipronil

### 2. STATEMENT OF ACTIVE AND SUBSTANCES

Each pipette contains 50 mg Fipronil

#### 3. PHARMACEUTICAL FORM

Spot-on solution

### 4. PACKAGE SIZE

- 1 pipette
- 2 pipettes
- 3 pipettes
- 4 pipettes
- 5 pipettes
- 6 pipettes

#### 5. TARGET SPECIES

Cats over 1kg and over 2 months old.

#### 6. INDICATION(S)

Flea & Tick treatment Kills fleas for 5 weeks

Kills ticks within a week

Bob Martin Clear Spot-on Solution 50 mg for Cats is for killing fleas and European Meadow Ticks on your cat. Applied at the back of the neck and between the shoulders, each treatment provides protection against fleas for up to 5 weeks and against the European Meadow Tick within 1 week of application. Kills fleas and is clinically proven to be effective within 48 hours.

Suitable for use in homes with both cats and dogs.

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

<u>Directions for use:</u> For external use only. <u>Thermoformed pipettes</u>



### STEP 1

Clear Spot-on must be applied at 2 points, at the base of the back of the head, and between the shoulder blades. If the cat is wearing a collar, remove it first so that it does not restrict application.



### STEP 2

Remove a single pipette from the pack. Hold the pipette upright and allow any liquid in the neck of the pipette to drain into the main body. Continue holding the pipette upright and snap off the tip.



# STEP 3

Part your cat's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half of the pipette at one point and half at the second point. Squeeze the pipette several times to ensure dosing is complete. Avoid applying onto the fur and do not rub into the skin, as this will reduce the product's performance. Do not allow pets to lick each other after treatment.

#### Polypropylene pipettes



- 1. Clear Spot-on must be applied at 2 points at the base of the back of the head and between the shoulder blades. If the cat is wearing a collar remove it first so that it does not restrict application.
- 2. Remove a single pipette from the pack. Hold the pipette upright and snap off the top section of the cap opening the pipette.
- 3. Part your cat's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half of the pipette at one point and half at the second point. Squeeze the pipette several times to ensure dosing is complete. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance. Do not allow cats to lick each other after treatment.

Regular treatment of all cats and dogs in the home together with regular vacuuming of your pet's bedding and resting areas is needed to protect your pet and home from fleas. If there is an existing and heavy infestation in your home it may also be necessary to treat the home with an approved home flea product.

Read the enclosed package leaflet before use for full instruction and all warnings, including user warnings. The dircetions for use and user safety warnings can also be found on the inner flap of the carton and should be read before each use.

# 8. WITHDRAWAL PERIOD

# 9. SPECIAL WARNING(S), IF NECESSARY

# O not use on rabbits!

Do not use this product on kittens less than 2 months old or weighing less than 1kg.

Treated cats should not be handled or played with until the application site has dried. Therefore, evening application is recommended. Treated cats should not be allowed to sleep with owners, especially children.

This product can cause mucous membrane and eye irritation. Do not get the product on your skin or in your eyes or mouth. If skin contact does occur wash it off quickly and thoroughly with soap and water. In case of accidental eye contact, immediately and thoroughly flush the eyes with clean water. If eye irritation continues seek medical advice and show the package leaflet or the packaging to the doctor.

Do not eat, drink or smoke whilst using this product.

Wash hands thoroughly after use.

People with a known hypersensitivity to Fipronil or any of the other ingredients should avoid contact with the veterinary medicinal product.

Do not use if you know that your pet has a known hypersensitivity to Fipronil or any other ingredient.

## 10. EXPIRY DATE

EXP: end {month/year}

### 11. SPECIAL STORAGE CONDITIONS

Store below 25°C, in a dry place and in the original packaging

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

Fipronil may adversely affect aquatic organisms. Dispose of waste materials in accordance with local requirements.

# 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 Ltd Brentwood House Lower Philips Road Whitebirk Industrial Estate Blackburn Lancashire BB1 5UD UK

# 16. MARKETING AUTHORISATION NUMBER

Vm 52797/5003

#### 17. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

#### OTHER INFORMATION

Made by Pet's Choice Limited in the UK under license from Martin & Martin Holdings Bob Martin is a registered trade mark of Martin & Martin Holdings. Since 1892 Bob Martin has provided vet-quality healthcare solutions for happy, healthy pets.

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

# PIPETTE LABEL

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Spot-on Solution 50 mg for Cats Fipronil

# 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg

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

50 mg

# 4. ROUTE(S) OF ADMINISTRATION

Spot-on

# 5. WITHDRAWAL PERIOD

N/A

# 6. BATCH NUMBER

Batch No: {number}

# 7. EXPIRY DATE

EXP:

# 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

# **PVC BLISTER WITH FOIL SEAL**

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Spot-on Solution 50 mg for Cats Fipronil

### 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pets Choice Limited

#### 3. EXPIRY DATE

EXP: {month/year}

### 4. BATCH NUMBER

Batch No: {number}

### 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET FOR: Bob Martin Clear Spot-on Solution 50 mg 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 Ltd Brentwood House Lower Philips Road Whitebirk Industrial Estate Blackburn Lancashire BB1 5UD UK

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

Bob Martin Clear Spot-on Solution 50 mg for Cats

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

#### Active substance:

Fipronil	50 mg
<b>Excipients:</b> Butylhydroxyanisole E320 Butylhydroxytoluene E321	0.1 mg 0.05 mg

Clear, pale amber solution

# 4. INDICATION(S)

Flea & tick treatment Kills fleas Kills ticks

Bob Martin Clear Spot-on Solution 50 mg for Cats is for killing fleas and European Meadow Ticks on your cat. Applied at the back of the cat's neck and between the shoulders, each treatment provides protection against fleas for up to 5 weeks.

Kills fleas and is clinically proven to be effective in 48 hours. Kills European Meadow Ticks within 1 week of application.

Bob Martin Clear Spot-on can be used on cats over 2 months old. Suitable for use in homes with both cats and dogs.

#### 5. CONTRAINDICATIONS

Do not use this product on kittens less than 2 months old or weighing less than 1kg. Do not use if you know that your cat has a known hypersensitivity to Fipronil or any other inaredient.

Do not use at the same time as other flea products which are applied directly onto the cat's skin.



Onot use on rabbits as death may occur!

Do not apply to any area of your cat's skin that is damaged (scratched, reddened, broken).

Do not use on sick or convalescent animals.

#### **ADVERSE REACTIONS** 6.

The product tastes extremely bitter and could make the cat salivate (drool) if the treated cat or another pet were to lick the skin soon after application. The drooling will usually disappear after a short while.

In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur either where the product was applied or more widely across the animal. Excessive salivation and nervous signs such as depression, hypersensitivity, vomiting or heavy breathing have been reported exceptionally.

#### **TARGET SPECIES** 7.

For cats

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

Use one pipette 0.5 ml per cat, applied to the skin as directed.

#### 9. ADVICE ON CORRECT ADMINISTRATION

For external use only.

To safeguard your health and that of your cat please read this leaflet carefully before you apply the product to your cat.

#### How should I use Bob Martin Clear Spot-on?

Check that your cat is at least 2 months old AND weighs more than 1 kg.

# Thermoformed pipettes



1. Clear Spot-on must be applied at 2 points, at the base of the back of the cat's head, and between the shoulder blades. If the cat is wearing a collar, remove it first so that it does not restrict application.



2. Remove a single pipette from the pack. Hold the pipette upright and allow any liquid in the neck of the pipette to drain into the main body. Continue holding the pipette upright and snap off the tip.



3. Part your cat's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half of the pipette at the back of the cat's neck and half between the cat's shoulders. Squeeze the pipette several times to ensure dosing is complete. Avoid applying onto the fur and do not rub into the skin, as this will reduce the product's performance. Do not allow cats to lick each other after treatment.

#### Polypropylene pipettes



1. Clear Spot-on must be applied at 2 points – at the base of the back of the head and between the shoulder blades. If the cat is wearing a collar remove it first so that it does not restrict application.

- 2. Remove a single pipette from the pack. Hold the pipette upright and snap off the top section of the cap opening the pipette.
  - 3. Part your cat's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half of the pipette at one point and half at the second point. Squeeze the pipette several times to ensure dosing is complete. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance. Do not allow cats to lick each other after treatment.

Avoid excessive wetting of the hair; occasionally some stickiness of crystals may be seen but these will usually disappear within 48 hours.

Avoid frequent shampooing or swimming

#### Is clear Spot-on all I need?

Regular treatment of all cats and dogs in the home together with regular vacuuming of your pet's bedding and resting areas is needed to protect your pet and home from fleas. If there is an existing and heavy infestation in the home it may also be necessary to treat the home with an approved home flea product.

### How often should I use Clear Spot-on?

This product provides protection from fleas for 5 weeks. The minimum interval between treatments is 4 weeks.

#### 10. WITHDRAWAL PERIOD

# 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Store below 25°C, in a dry place and in the original packaging.

#### 12. SPECIAL WARNING(S)

Special precautions for use in animals

Do not allow recently treated pets to groom each other.

Only apply the product as instructed so that your pet cannot lick it off.

Take care to ensure that the liquid in the pipette does not come in contact with the pet's eyes or mouth. If it does come into contact, wash it off quickly and thoroughly. If necessary seek veterinary advice.

### Pregnancy and lactation

Not recommended for use in pregnant and nursing cats. Consult your veterinary surgeon advice.

If signs of disease persist or appear, consult a veterinary surgeon.

### <u>Overdose</u>

The safety of this product has not been investigated in studies where overdose or repeated dosing were used due to the well-known safety profile of the active substance and other ingredients.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals</u>

Treated animals should not be handled or played with until the application site has dried. Therefore, evening application is recommended. Treated cats should not be allowed to sleep with owners, especially children.

This product can cause mucous membrane and eye irritation. Do not get the product on your skin or in your eyes or mouth. If skin contact does occur wash it off quickly and thoroughly with soap and water. In case of accidental eye contact, immediately and thoroughly flush the eyes with clean water. If eye irritation continues seek medical advice and show the package leaflet or the packaging to the doctor.

Do not eat, drink or smoke whilst using this product.

Wash hands thoroughly after use.

People with a known hypersensitivity to Fipronil or any of the other ingredients should avoid contact with the veterinary medicinal product.

For animal treatment only.

#### Other precautions

This product may mark certain materials including leather, fabrics, plastics and finished surfaces. Allow application site to dry before permitting contact with these materials.

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

Dispose of empty packaging and any remaining product in accordance with local requirements. Fipronil may adversely affect 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

September 2021

# 15. OTHER INFORMATION

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

Revised: September 2021 AN: 02264/2020

Approved: 29/09/21

D. Austro-