# ANNEX III LABELLING AND PACKAGE LEAFLET

# A. LABELLING

# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

#### **CARTON BOX or BLISTER CARD**

#### For external use only. Cats over 1kg

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

Bob Martin Clear Plus 50 mg/ 60 mg Spot-on Solution for Cats and Ferrets Fipronil

(S)-methoprene

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains 50 mg fipronil and 60 mg (S)-methoprene.

#### 3. PHARMACEUTICAL FORM

Spot-on solution.

#### 4. PACKAGE SIZE

1 pipette

2 pipettes

3 pipettes

4 pipettes

5 pipettes

6 pipettes

#### 5. TARGET SPECIES

For cats and ferrets.

#### 6. INDICATION(S)

Fleas & ticks

Treat & protect

Kills fleas for 4 weeks

Kills ticks for 2 weeks

Kills flea eggs for 6 weeks

Kills fleas and ticks, as well as bitting lice on cats only.

Each treatment kills fleas within 24 hours and for up to 4 weeks, and ticks within 48 hours and for up to 2 weeks (4 weeks for ferrets).

It contains Fipronil plus (S)-methoprene, an insect growth regulator, which inhibits the development of flea eggs, larvae and pupae for up to 6 weeks after application, preventing re-infestation of the pet's home environment.

Suitable for cats over 8 weeks old and on ferrets over 6 months old.

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

#### Directions for use:

# <u>Thermoformed pipettes:</u>

#### STEP1

Bob Martin Clear Plus must be applied at 2 points, at the base of the back of the pet's head and between the shoulder blades. If the pet 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 pet'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. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance.



#### Polypropylene pipettes







- 1. Bob Martin Clear Plus must be applied at 2 points at the base of the back of the pet's head and between the shoulder blades. If the pet is wearing a collar remove it first so that it does not restrict application.
- 2. Remove a single pipette from the pack. Hold pipette upright and snap off the top section of the cap opening the pipette.
- 3. Part your pet'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. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance.

# Apply to an area where the animal cannot lick it off and do not allow pets 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.

# 8. WITHDRAWAL PERIOD(S)

# 9. SPECIAL WARNING(S), IF NECESSARY

# Onot use on rabbits as may cause death!

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

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

#### **USER SAFETY- Please read before every use**

Keep pipettes in original packaging until ready to use.

This product can cause mucous membrane, skin 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 the eye irritation continues, seek medical advice and show the package leaflet or the packaging to the doctor.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with this product.

Wash hands after use.

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

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

#### 10. EXPIRY DATE

EXP: end {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in a dry place and in the original package.

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

Dispose of waste material in accordance with local requirements. Fipronil and (S)-methoprene should not enter water courses as this may be dangerous for fish or other aquatic organisms.

# 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 52797/4010

#### 17. MANUFACTURER'S BATCH NUMBER

Batch No: {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 Plus 50 mg/ 60 mg Spot-on Solution for Cats and Ferrets Fipronil (S)-methoprene
2. QUANTITY OF THE ACTIVE SUBSTANCE(S)
50 mg/60 mg
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES
50 mg/60 mg
4. ROUTE(S) OF ADMINISTRATION
Spot-on
5. WITHDRAWAL PERIOD(S)
6. BATCH NUMBER
Batch No: {number}
7. EXPIRY DATE
EXP: {month/year}
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 Plus 50 mg/ 60 mg Spot-on Solution for Cats and Ferrets Fipronil (S)-methoprene

## 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:**

Bob Martin Clear Plus 50 mg/ 60 mg Spot-on Solution for Cats and Ferrets

# 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 Plus 50 mg/ 60 mg Spot-on Solution for Cats and Ferrets Fipronil

(S)-methoprene

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

Clear amber solution.

Each pipette of 0.5 ml contains:

### **Active substances:**

Fipronil 50.00 mg (S)-methoprene 60.00 mg

## **Excipients:**

Butylhydroxyanisole (E320) 0.10 mg Butylhydroxytoluene (E321) 0.05 mg

# 4. INDICATION(S)

Flea & tick treat & protect Kills fleas fast Kills ticks

Kills flea eggs

Bob Martin Clear Plus is for killing fleas and ticks on your pet and treatment of infestations with biting lice on cats. Each treatment kills fleas within 24 hours and for up to 4 weeks, and ticks within 48 hours and for up to 2 weeks in cats and 4 weeks in ferrets.

Inhibits the development of flea eggs, larvae and pupae for 6 weeks after application preventing re-infestation of the pet's home environment.

Bob Martin Clear Plus can be used on cats over 8 weeks old and ferrets over 6 months old.

#### 5. CONTRAINDICATIONS

Do not use this product on kittens less than 8 weeks old and/or weighing less than 1 kg.

Do not use this product on ferrets less than 6 months old.

Do not use on unwell animals or animals recovering from an illness or operation.

Do not use in rabbits, as adverse reactions or even death could occur. In absence of studies, the use of the product is not recommended in species other than cats and ferrets.

Do not use in animals known to be allergic to the active substances (Fipronil and (S)-methoprene) or to any of the other ingredients (excipients).

#### 6. ADVERSE REACTIONS

Do not overdose.

Cats:

Among the very rare suspected adverse reactions, temporary skin reactions on the application site (scaling, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs) or vomiting have also 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 licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier .

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

Cats and Ferrets.

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

Use one pipette per cat/ferret, applied to the skin as directed.

## 9. ADVICE ON CORRECT ADMINISTRATION

For external use only.

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

#### **How should I use Bob Martin Clear Plus?**

Check that your cat is at least 8 weeks old AND weighs more than 1kg. Check that your ferret is at least 6 months old.

#### Thermoformed pipettes:

1. Bob Martin Clear Plus must be applied at 2 points, at the base of the back of the cat's head and between the shoulder blades. If the pet 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 pet'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. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance.



## Polypropylene pipettes







- 1. Bob Martin Clear Plus must be applied at 2 points at the base of the back of the pet's head and between the shoulder blades. If the pet 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 pet'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. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance. Apply to an area where the animal cannot lick it off and do not allow pets to lick each other after treatment.

Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

It is not recommended to bath animals within 2 days after application of the product.

#### Is Bob Martin Clear Plus all I need?

Regular treatment of all cats, ferrets 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. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time.

#### How often should I use Bob Martin Clear Plus?

Cats: This product provides protection from fleas for 4 weeks and ticks for 2 weeks. Ferrets: This product provides protection from fleas and ticks for 4 weeks. The minimum interval between treatments is 4 weeks.

# 10. WITHDRAWAL PERIOD(S)

#### 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 C.

Store in a dry place and in the original package.

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.

# 12. SPECIAL WARNING(S)

#### Special warnings for each target species

Avoid frequent shampooing or swimming.

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

# Special precautions for use in animals

For animal treatment only.

Take care to ensure that the liquid in the pipette does not come into 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.

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

Do not allow recently treated pets to groom each other.

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

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

Keep pipettes in original packaging until ready to use.

This product can cause mucous membrane, skin 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 the eye irritation continues, seek medical advice and show the package leaflet or the packaging to the doctor.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with this product. Avoid contents coming into contact with the fingers. If it occurs, wash hands with soap and water.

Wash hands after use.

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

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

## Pregnancy and lactation:

#### Cats:

The product can be used during pregnancy. The safety of the product for kittens of less than 8 weeks of age in contact with a treated nursing female is not established. Special care should be taken in this case.

#### Ferrets:

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

#### Interaction with other medicinal products and other forms of interaction:

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

#### Overdose (symptoms, emergency procedures, antidotes):

#### Cats

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

In ferrets

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

# 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 waste material in accordance with local requirements. Fipronil and (S)-methoprene should not enter water courses as this may be dangerous for fish or other aquatic organisms.

#### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

#### 15. OTHER INFORMATION

Blister cards or carton boxes of 1, 2, 3, 4, 5 or 6 pipettes.

Not all pack sizes may be marketed.

Approved: 27 June 2023