# PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARTON CARTON

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

Advantage 400 mg Spot-on Solution for Extra Large Dogs

# 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Ingredient: Imidacloprid 100 mg/ml

#### 3. PHARMACEUTICAL FORM

Spot-on solution.

# 4. PACKAGE SIZE

2, 3, 4, 6 x 4.0 ml

#### **ACTIVE INGREDIENTS:**

This pack contains 2, 3, 4, 6 tubes, each containing a solution of imidacloprid (equivalent to 400 mg imidacloprid /tube).

#### 5. TARGET SPECIES

For Extra Large Dogs more than 25 kg

# 6. INDICATION(S)

Kills fleas on contact.

Kills flea larvae in the pet's immediate home surroundings.

Up to 12 weeks protection.

Protects your pet and home from fleas. Protects your pet and home.

Breaks the flea life cycle.

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

#### FOR BEST RESULTS

Weigh your pet accurately before use and use the correct tube size.



Remove one tube from the packaging. Hold tube in an upright position, twist and pull off the cap. Turn the cap over and push down and twist to break the seal on the tube.

With your dog in a standing position, part the coat at 3 sites along the dog's backline between the shoulders and base of the tail. Place the tip of the tube on the skin and apply all of the solution evenly between the 3 sites.

Apply only to undamaged skin and do not rub in as this could reduce efficacy.

Monthly treatment of <u>all</u> cats and dogs in the household with Advantage 400 mg Spot-on, together with regular vacuuming of pet's bedding and resting areas are usually all that is needed to protect both your pet and home from fleas. If there is a particularly heavy infestation in the home it may be necessary to also treat the home with a suitably approved home flea product.

#### 8. WITHDRAWAL PERIOD

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

**IMPORTANT:** Use correctly to safeguard the health of you and your pet. Read the enclosed Product Information Leaflet carefully before use.

For external use only.

#### 10. EXPIRY DATE

Expiry: {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

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

# 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

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#### 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

#### 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

#### 16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4129

#### 17. MANUFACTURER'S BATCH NUMBER

Batch No.: {number}

Distributor: Bob Martin (UK) Ltd,

Advantage 400 mg Spot-on Solution for Extra Large Dogs is easy to use and has a specially developed formulation that acts quickly to kill fleas on your pet and target flea larvae in the pet's immediate home surroundings. It is this Double Action that makes the product effective in protecting your pet from fleas. Effective and gentle – Advantage 400 mg Spot-on can be used on puppies from 8 weeks of age.

Available in 4 packs to suit all breeds and sizes of cats and dogs.

# PRODUCT PERFORMANCE

Each treatment will protect your pet from fleas for up to 4 weeks.

Specially developed Double Action Formula

- 1. Kills fleas on contact Kills fleas before they can lay eggs breaking the flea life cycle.
- 2. Kills flea larvae in the pet's immediate surroundings e.g. bedding or favourite resting areas prevention re-infestation.

# YOUR GUARANTEE

We are confident that you will be delighted with your purchase of this product but if for any reason, this product reaches you in an unsatisfactory condition, please return it to us and we will promptly replace it or refund your money. Your statutory rights are not affected. Write to FREEPOST Bob Martin (no address required).

**CARELINE:** For help and advice on flea control for your pets, call Bob Martin on 0844 748 0108.

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS:

# **TUBE LABEL**

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

Advantage 400 mg Spot-on Solution for Extra Large Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 400 mg imidacloprid per 4.0 ml.

- 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES
- 4.0 ml
- 4. ROUTE(S) OF ADMINISTRATION
- 5. WITHDRAWAL PERIOD
- **6. BATCH NUMBER**

BN: {number}

7. EXPIRY DATE

Exp: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

For external use only.

Vm 00879/4129

**AVM-GSL** 

Bob Martin (UK) Ltd.

# MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

# **BLISTER FOIL**

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

Advantage 400 mg Spot-on Solution for Extra Large Dogs.

Contains 400 mg Imidacloprid per 4.0 ml.

#### 2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

Exp.: {month/year}

4. BATCH NUMBER

BN: {number}

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

For animal treatment only For external use only.

Keep container in outer carton.

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Vm 00879/4129

Bob Martin (UK) Ltd.

3 x 4.0 ml tubes

# <u>PACKAGE LEAFLET FOR: Advantage 400 mg Spot-on Solution for Extra</u> Large Dogs

# 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA holder: Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA United Kingdom

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

Advantage 400 mg Spot-on Solution for Extra Large Dogs<sup>1</sup>

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

#### Each tube contains

Advantage 400 mg Spot-on	Tube	Imidacloprid
For cats and small dogs < 4 kg	0.4 ml	40 mg
For small to medium dogs 4 – 10 kg	1.0 ml	100 mg
For large dogs 10 – 25 kg	2.5 ml	250 mg
For extra large dogs > 25 kg	4.0 ml	400 mg

#### 4. INDICATION(S)

#### **Product Performance**

- Each treatment will protect your pet from fleas for up to 4 weeks.
- Specially developed Double Action Formula
  - 1. Kills fleas on contact
    - Kills fleas before they can lay eggs breaking the flea life cycle.
  - 2. Kills flea larvae in the pet's immediate surroundings e.g. bedding or favourite resting areas prevention re-infestation.

#### 5. CONTRAINDICATIONS

Do not treat unweaned kittens or puppies that are less than 8 weeks old. Do not use simultaneously with other flea products which are applied directly onto the animal.

 $<sup>^{</sup>m 1}$  A single package leaflet is used for all Advantage Spot-on Solution products

#### 6. ADVERSE REACTIONS

The product tastes extremely bitter and could make a pet salivate (drool) if the treated pet or another pet were to lick the skin soon after application. This is not a dangerous sign and does not require any treatment. 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. Agitation and, in dogs, disorientation have also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported exceptionally.

#### 7. TARGET SPECIES

Dogs and cats.

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

#### For Best Results

Weight your pet accurately before use and use the correct tube size.

#### 9. ADVICE ON CORRECT ADMINISTRATION

Remove one tube from the packaging. Hold tube in an upright position, twist and pull off the cap. Turn cap over and push down and twist to break seal on the tube.



#### For Cats less than 4 kg, apply one tube.

Part the hair on your cat's neck at the base of the head. Place the tip of the tube on the skin and apply all of the solution directly onto the skin.

For Cats weighing 4 kg and over, 2 tubes are required for each treatment Both tubes should be applied to the same spot at the base of the head.





# For Dogs less than 25 kg.

With your dog in the standing position, part the coat between the shoulder blades. Place the tip of the tube on the skin and apply all of the solution directly onto the skin.

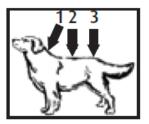




# For Dogs over 25 kg.

With your dog in a standing position, part the coat at 3 sites along the dog's backline between the shoulders and base of the tail. Place the tip of the tube on the skin and apply all of the solution evenly between the 3 sites.





Apply only to undamaged skin and do not rub in as this could reduce efficacy.

Monthly treatment of all cats and dogs over 8 weeks in the household with Advantage 400 mg Spot-on together with regular vacuuming of pet's bedding and resting areas are usually all that is needed to protect both your pet and home from fleas.

If there is a particularly heavy flea infestation in the home, it may be necessary to also treat the home with a suitable approved home flea product.

Regular use of Advantage 400 mg Spot-on should prevent the need to use any other flea treatment products.

#### How Often to Use?

Use monthly as part of a flea control programme.

The efficacy of the product may be reduced if the animal becomes very wet. If retreatment becomes necessary earlier than 4 weeks, treatment may be repeated. Do not apply more frequently than weekly.

Use the calendar stickers included the pack to keep details of when the pets are treated and due for retreatment.

# 10. WITHDRAWAL PERIOD(S)

# 11. SPECIAL STORAGE PRECAUTIONS

Store away from food, drink or animal feeding stuffs.

Do not use after expiry date.

Keep container in outer carton.

# 12. SPECIAL WARNING(S)

#### For Safe Use

Do not allow recently treated pets to groom each other.

Take care to ensure that the liquid in the tube does not come into contact with the pet's eyes or mouth.

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

Consult your veterinary surgeon before using in pregnant or nursing animals.

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

### **User Safety**

One of the ingredients of this product may cause skin sensitisation, irritation or tingling.

Do not get the products on your skin or in your eyes or mouth.

If you get the product on your skin wash it off with soap and water.

If you get the product in your eyes, wash your eyes thoroughly with clean water.

If the product causes any irritation to your skin or eyes that is persistent, contact your doctor.

If the product is swallowed, contact your doctor immediately.

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

Wash hands thoroughly after use.

After application, do not stroke or groom pets until the site of application is dry (typically within an hour or so).

#### **General Precautions**

Keep out of reach of children.

For animal treatment only.

For external use only.

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

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment.

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

Dispose of empty packaging and any remaining product in the household refuse.

# 14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

#### 15. OTHER INFORMATION

#### **Product Details**

Advantage 400 mg Spot-on Solution for Extra Large Dogs

For cats and small dogs less than 4 kg	Vm 00879/4128
For small to medium dogs 4 – 10 kg	Vm 00879/4126
For large dogs 10 – 25 kg	Vm 00879/4127
For extra large dogs more than 25 kg	Vm 00879/4129

Each pack contains 3 tubes each containing a 10% w/v solution of imidacloprid.

# Protects your pet and home

Advantage 400 mg Spot-on is easy to use and has a specially developed formulation that acts quickly to kill fleas on your pet and target flea larvae in the pet's immediate home surroundings. It is this Double Action that makes the product effective in protecting your pet from fleas.

Effective and gentle – Advantage 400 mg Spot-on Solution can be used on puppies and kittens from 8 weeks of age.

Available in 4 packs to suit all breeds and sizes of cats and dogs.

#### **Your Guarantee**

We are confident that you will be delighted with your purchase of this product but if for any reason, this product reaches you in an unsatisfactory condition, please return

it to us and we will promptly replace it or refund your money. Your statutory rights are not affected. Write to FREEPOST Bob Martin (no address required). **CARELINE:** For help and advice on flea control for your pets, call Bob Martin on 0844 748 0108.

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Bob Martin (UK) Ltd.

Approved 27 November 2024 *Gavin Hall*