PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 3, 4, 6 and 24 pipette(s) **– 1.0 ml pipettes**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearspot 100 mg Spot-On Solution for Medium Dogs
Imidacloprid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Imidacloprid : 100 mg
Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-On Solution.

4. PACKAGE SIZE

1 x 1.0 ml
3 x 1.0 ml
4 x 1.0 ml
6 x 1.0 ml
24 x 1.0 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Only for those countries where the product is available without prescription.

For dogs of 4 kg to less than 10 kg:
Prevention and treatment of flea (*Ctenocephalides felis*) infestations.
The product shows immediate insecticidal effect and persistent insecticidal activity for up to 4 weeks in dogs. The product may be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Disposal: Read the package leaflet

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

Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

<to be completed nationally>

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 1.0 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearspot 100 mg Spot-On Solution for Medium Dogs
Imidacloprid

2. QUANTITY OF ACTIVE SUBSTANCE(S)

One 1.0 ml pipette contains 100 mg Imidacloprid

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

1.0 ml.

4. ROUTE(S) OF ADMINISTRATION

For external use only.
Spot-on use
<Pictogram of a spot-on pipette>

5. WITHDRAWAL PERIOD

-

6. BATCH NUMBER

BN

7. EXPIRY DATE

EXP {mm/yyyy}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

<Pictogram of a dog>

9. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1.0 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearspot 100 mg Spot-On Solution for Medium Dogs
Imidacloprid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook

3. EXPIRY DATE

EXP {mm/yyyy}

4. BATCH NUMBER

XXXX XXX

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

<Pictogram of a dog>

6. PHARMACEUTICAL FORM

<Pictogram of a spot-on pipette>

7. VOLUME

1.0 ml

8. TARGET ANIMAL WEIGHT RANGE

≥ 4 < 10 kg

PACKAGE LEAFLET FOR:

Clearspot 100 mg Spot-On Solution for Medium 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 and manufacturer responsible for batch release:

Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
United Kingdom

Manufacturer responsible for batch release:

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearspot 100 mg Spot-On Solution for Medium Dogs
Imidacloprid

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

One 1.0 ml pipette contains :
Active substance :
Imidacloprid 100 mg
Excipients :
Butylhydroxytoluene (E321) 1.0 mg

Spot-on solution
A clear pale yellow to yellow solution

4. INDICATIONS

For dogs of 4 kg to less than 10 kg:
Prevention and treatment of flea (*Ctenocephalides felis*) infestations.
The product shows immediate insecticidal effect and persistent insecticidal activity for up to 4 weeks in dogs. The product may be used as part of a

treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

5. CONTRAINDICATIONS

Do not treat unweaned puppies of less than 8 weeks of age.
Do not use in animals that are known to be hypersensitive to the active substance or any of the excipients

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment.
On very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation and disorientation has also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported exceptionally in dogs.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Spot-on use

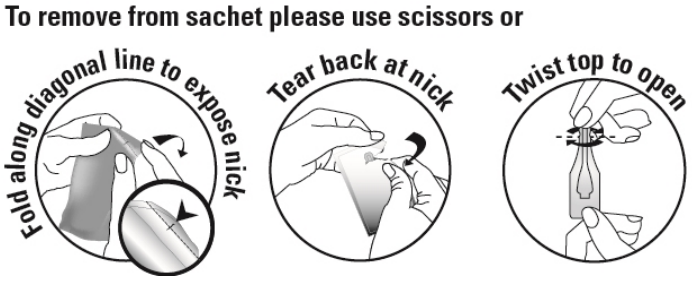
Dog (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
< 4 kg	Clearspot 40 mg Spot-On Solution For Small Cats and Small Dogs	1 x 0.4 ml	minimum of 10
≥ 4 < 10 kg	Clearspot 100 mg Spot-On Solution For Medium Dogs	1 x 1.0 ml	minimum of 10
≥ 10 < 25 kg	Clearspot 250 mg Spot-On Solution For Large Dogs	1 x 2.5 ml	minimum of 10
≥ 25 < 40 kg	Clearspot 400 mg Spot-On Solution For Very Large Dogs	1 x 4.0 ml	minimum of 10
≥ 40 kg	Clearspot 400 mg Spot-On Solution For Very Large Dogs	2 x 4.0 ml	minimum of 10

Treatment should be repeated after 4 weeks.

The product shows immediate insecticidal effect and persistent insecticidal activity for up to 4 weeks in dogs. Should re-treatment become necessary earlier than 4 weeks, do not re-treat more frequently than weekly.

Method of Administration

Hold upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Break back the snap-off top from the Spot-On Solution pipette along the scored line



<u>For dogs less than 25 kg body weight:</u>
With the dog in the standing position, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.

<u>For dogs of 25 kg body weight and greater:</u>
The dog should be standing for easy application. The entire contents of the pipette(s) should be applied evenly to three or four spots all located at different application sites along the dog's backline from the shoulder to the base of the tail. At each spot part the coat until the skin is visible.

Place the tip of the pipette on the skin and gently squeeze to expel a portion of the contents directly onto the skin.

For all dogs:
Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application will minimize the opportunity for the dog to lick the product.

9. ADVICE ON CORRECT ADMINISTRATION

Part the hair on the receiving animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.

Application at the base of the skull will minimize the opportunity for the animal to lick the product.

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 disappear within 24 hours post application.

Animals should be weighed accurately prior to treatment.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date which is stated on the carton.

12. SPECIAL WARNINGS

Special precautions for use in animals

This product is for topical use only and should not be administered orally.
Apply only to undamaged skin.
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
Do not allow recently treated animals to groom each other.

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

Do not massage the application site.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions (for example, irritation, tingling).
Avoid contact between the product and skin, eyes or mouth.
Do not eat, drink or smoke during application.
Wash off any skin contamination with soap and water.
If the product gets into eyes accidentally, the eyes should be thoroughly flushed with water.
If skin or eye irritation persists, obtain medical attention.
If the product is accidentally swallowed, obtain medical attention immediately.
Wash hands thoroughly after use.
After application, do not stroke or groom animals until application site is dry.
People with known skin sensitivity may be particularly sensitive to the product.

Overdose (symptoms, emergency procedures, antidotes)

In dogs, no adverse clinical signs were produced by doses of up to five times the therapeutic dose when administered topically to pups on three occasions, fourteen days apart.

In rare cases of overdose or licking of treated hair, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.
Poisoning following inadvertent oral uptake in either man or animals is unlikely. In this event, treatment should be symptomatic. There is no known specific antidote but administration of activated charcoal may be beneficial.

Interaction with other medicinal products and other forms of interaction

Based upon data from other similar products, no incompatibility has been observed between imidacloprid applied at twice the recommended dose and lufenuron, febantel, pyrantel and praziquantel. Compatibility of imidacloprid

with a wide range of routine treatments under field conditions including vaccination has also been shown.

Other precautions

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended. In order to reduce further the environmental challenge, it is recommended that all dogs, cats and rabbits in the household are treated with a suitable product.
Treatment of nursing bitches controls flea infestations on both dam and offspring.
After 48 hours the product remains effective if the animal becomes wet. However, in cases of frequent swimming, bathing or shampooing, re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.
Imidacloprid is toxic to aquatic organisms. Treated dogs should not be allowed to enter surface water for 48 hours after treatment, to avoid adverse effects on aquatic organisms.

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

Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to a group of chloronicotinyl compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine.

Mode of Action
The substance has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS). The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptor sites and the postulated poor penetration through the blood/brain barrier in mammals, it has virtually no effect on the mammalian CNS. The minimal pharmacological activity in mammals is supported by safety studies involving systemic administration of sub-lethal doses to rabbits, mice and rats.

In further studies, in addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the pet's surroundings are killed following contact with a treated animal.

Package Information

1.0 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminate and a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachet composed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.

Boxes of 1, 3, 4, 6 and 24 pipettes.

Not all pack sizes may be marketed.

Distributed by:

<to be completed nationally>