# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearspot 100 mg Spot-on Solution for Medium Dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 1.0 ml pipette contains :

| | |
|---|---|
| **Active substance :** | |
| Imidacloprid | 100 mg |
| **Excipients :** | |
| Butylhydroxytoluene (E321) | 1.0 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-On Solution
A clear pale yellow to yellow solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs

### 4.2 Indications for use, specifying the target species

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.

### 4.3 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

### 4.4 Special warnings

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.

## 4.5 Special precautions for use

i. 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.

ii. 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.

iii. Other precautions

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.

## 4.6 Adverse reactions (frequency and seriousness)

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 a few minutes without treatment (see also section 4.9 *Amounts to be administered and administration route*).
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.

## 4.7 Use during pregnancy, lactation or lay

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating bitches together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

## 4.8 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.

## 4.9 Amounts to be administered and administration route

Spot-on use.
Animals should be weighed accurately prior to treatment.

*Dosage and Treatment Schedule*

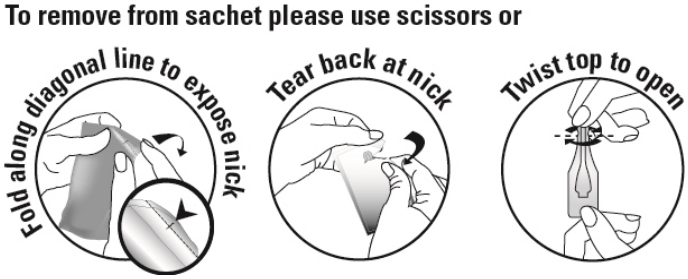
| Dog (kg bw) | Product | Number of Pipettes | Imidacloprid (mg/kg bw) |
|---|---|---|---|
| < 4 kg | Clearspot 40 mg Spot-On Solution For Small Cats and Small Dogs | 1 x 0.4 ml | minimum of 10 |
| ≥ 4 < 10 kg | Clearspot 100 mg Spot-On Solution For Medium Dogs | 1 x 1.0 ml | minimum of 10 |
| ≥ 10 < 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.




For dogs less than 25 kg body weight:
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.


For dogs of 25 kg body weight and greater:
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 a few minutes without treatment. Correct application will minimize the opportunity for the dog to lick the product.

### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

### 4.11 Withdrawal period(s)

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Ectoparasiticides for topical use; Imidacloprid
**ATCvet code:** QP53AX17

## 5.1 Pharmacodynamic properties

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.

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.

## 5.2 Pharmacokinetic particulars

The product is indicated for cutaneous administration. Following topical application in dogs, the solution is quickly distributed over the animal. Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption is very low, transient and not relevant for the clinical efficacy. This has been further demonstrated by a study in which fleas were not killed after having fed on previously treated animals once the animal's skin and fur had been cleaned of all active material.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Butylhydroxytoluene (E321)
Benzyl alcohol
Ethanol, anhydrous

## 6.2 Incompatibilities

None known.

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

## 6.4. Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

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.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

**Vm** 02000/4374

## 9. DATE OF FIRST AUTHORISATION

**Date:** 8 January 2014

## 10. DATE OF REVISION OF THE TEXT

**Date:** October 2014

30 October 2014