Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Exidot 250 mg Spot-on solution for Large Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2.5 ml pipette contains:

Active substance:		
Imidacloprid	250	mg
Excipients:		
Butylhydroxytoluene (E 321)	2.5	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Spot-on solution
A clear pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the prevention and treatment of flea infestations and for the treatment of biting lice *(Trichodectes canis)* on dogs weighing ≥ 10 to < 25 kg.
Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.
The product can 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 case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

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 cats, pet rabbits and dogs in the household are treated. Treatment of nursing bitches controls flea infestations on both dam and offspring.
The product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, 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.
In case of biting lice infestation in dogs, a veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.
Use the appropriate product for Dogs based on bodyweight (see section 4.9).

4.5 Special precautions for use

Special precautions for use in animals
For external use only.
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
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling) and/or eye irritation.
Avoid contact between the product and skin, eyes or mouth.
People with known hypersensitivity to the active ingredient or any of the excipients should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke during application.
Do not massage the application site. After application, do not stroke or groom animals until application site is dry.
Wash off any skin contamination with soap and water. Wash hands thoroughly after use.
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.

Other precautions
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.
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.

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 some minutes without treatment. (see also section 4.9 *Amounts to be administered and administration route*).
In very rare occasions (less than 1 animal in 10,000 animals, including isolated reports) skin reactions such as hair loss, redness, itching and skin lesions may occur.
Agitation, excessive salivation and nervous signs such as incoordination, tremors and depression have also been reported very rarely.

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 interactions

No incompatibility has been observed between this product at twice the recommended dose and the following commonly used veterinary products: lufenuron, pyrantel and praziquantel and febantel. The compatibility of the product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

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)	Number of Pipettes	Imidacloprid (mg/kg bw)
≥ 10 to < 25 kg	1 x 2.5 ml	minimum of 10

Method of administration:

Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.
Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

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.
Correct application will minimise the opportunity for the dog to lick the product.
Apply only to undamaged skin.
Do not allow recently treated animals to groom each other.

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

No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.
In rare cases of overdose or licking of treated fur, 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 or IMMUNOLOGICAL 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 sublethal doses to rabbits, mice and rats.
In further studies, in addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea activity 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

Following topical application in dogs, the solution is quickly distributed over the animal. 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 (E 321)
Benzyl alcohol (E 1519)
Propylene carbonate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store in the original package in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

6.5 Nature and composition of immediate packaging

A white pipette composed of a heat-formed shell of a polypropylene/cyclic olefin copolymer/polypropylene layer and a polyethylene/ethylene vinyl alcohol/polyethylene layer.
Cardboard Box with 1, 2, 3, 4, 6, 8, 9, 10, 12, 15, 18, 20, 21, 24, 30, 60, 90, 150 or 160 pipettes in individual foil sachets.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/138/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 November 2019

10 DATE OF REVISION OF THE TEXT