

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidaflea 40 mg Spot-on solution for Small Cats, Small Pet Rabbits & Small Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

Imidacloprid 40 mg

Excipients:

Butylhydroxytoluene (E 321) 0.4 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution

Clear yellow to slightly brownish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats, dogs and pet rabbits

4.2 Indications for use, specifying the target species

Cats & Pet Rabbits

Prevention and treatment of flea (*Ctenocephalides felis*) infestations in cats of less than 4 kg body weight.

Treatment of flea infestations in rabbits of less than 4 kg body weight.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks on cats and up to one week on pet rabbits.

Dogs

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*) on dogs of less than 4 kg body weight.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

4.3 Contraindications

Cats & Pet Rabbits

Do not treat unweaned kittens of less than 8 weeks of age.

Do not use on pet rabbits of less than 10 weeks of age.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Dogs

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

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

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, dogs and rabbits in the household are treated.

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.

4.5 Special precautions for use

Special precautions for use in animals

This product is for topical use 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

This product can cause mucous membrane, skin and eye irritation.

Therefore, contact of the product with mouth, skin and eyes should be avoided.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

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

Do not smoke, drink or eat during application.

If contact with the skin occurs, wash hands with soap and water.

If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

Dispose of used pipettes immediately.

Wash hands after use.

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

4.6 Adverse reactions (frequency and seriousness)

The product is bitter tasting and salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment.

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 has also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported but exceptionally in cats.

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).

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with other flea products which are applied directly onto the animal.

4.9 Amounts to be administered and administration route

This product is for external use only and should not be administered orally. Animals should be weighed accurately prior to treatment.

Dosage and Treatment Schedule

Cat/Rabbit/Dog (kg body weight)	Product	Number of Pipettes	Advaprid (mg/kg body weight)
Less than 4 kg	Advaprid 40 for Small Cats and Small Pet Rabbits and Dogs	1 x 0.4 ml	minimum of 10

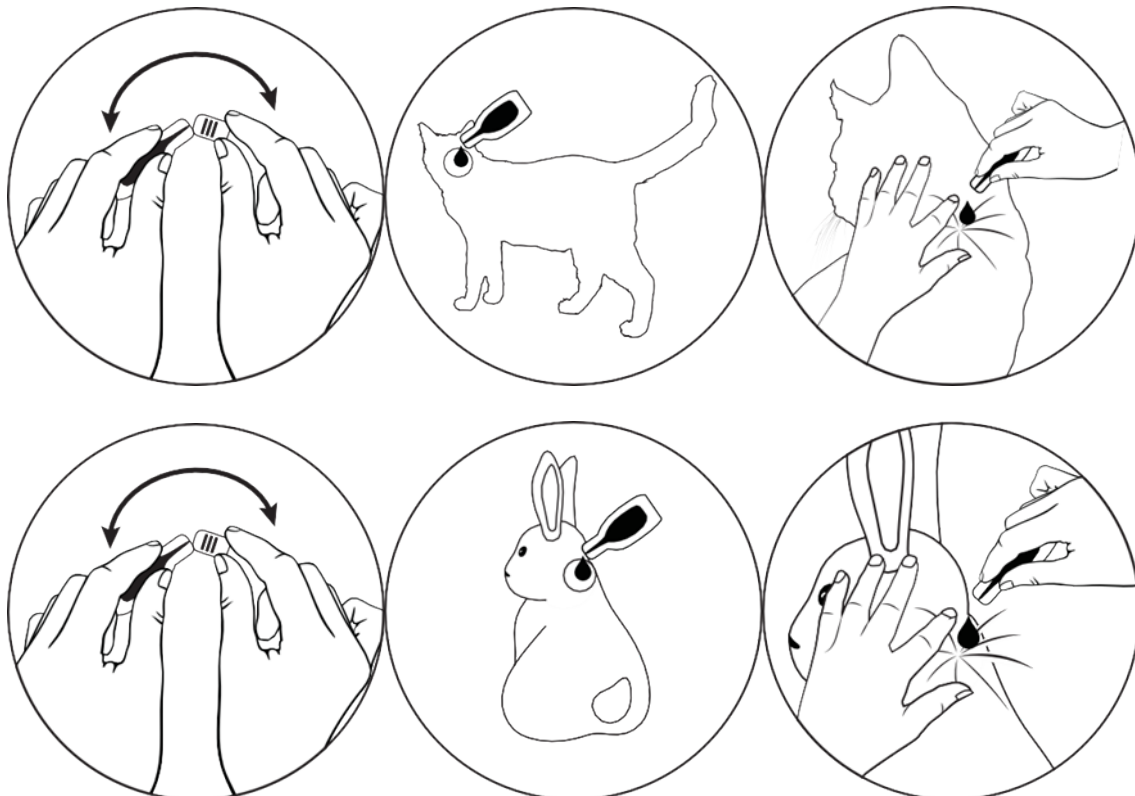
In cases of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Method of administration:

Cat and rabbits

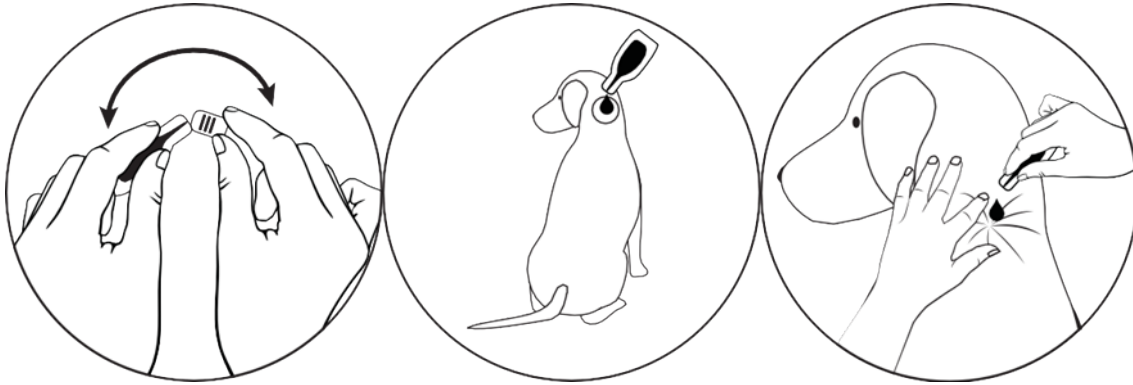
Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the hair on the animal's neck at the base of the skull until the skin is visible.

Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot. Correct application will minimise the opportunity for the animal to lick the product.



Dogs

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. 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 the pipette several times to empty its contents completely and directly onto the skin in one spot. Correct application will minimise the opportunity for the animal to lick the product.



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

Cats & Rabbits

In cats, no adverse clinical signs were produced using doses of five times the therapeutic level weekly for eight consecutive weeks.

In rabbits, no adverse clinical signs were seen using doses of up to 45 mg/kg body weight (4 times the therapeutic level) weekly for 4 consecutive weeks.

Dogs

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 in cats.

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)

Do not use on rabbits intended for human consumption.

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 nicotinic 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 nicotinic 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 cat's and dog'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 cats, 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 (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

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

6.5 Nature and composition of immediate packaging

A white pipette composed of a heat-formed shell of composed of a polypropylene/cyclic olefin copolymer/polypropylene layer and a polyethylene/ethylene vinyl alcohol/polyethylene layer.

Box with 1, 2, 3, 4, 6 pipettes in individual foil sachets.
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

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

EU Pharmaceuticals Ltd.
37 Geraldine Road
London
SW18 2NR

8. MARKETING AUTHORISATION NUMBER

Vm 39787/4075

9. DATE OF FIRST AUTHORISATION

3 July 2019

10. DATE OF REVISION OF THE TEXT

3 July 2019

Approved 3 July 2019

