

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Defendog Cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Permethrin technical (cis : trans 40 : 60) 1.88 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

A clear to pale cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

Treatment and prevention of flea infestations in dogs. Protection against flea reinfestation will be provided for 42 days after treatment.

4.3 Contraindications

Do not use on cats.

Do not use on puppies under 3 months of age.

Do not use on sick or convalescent dogs.

Do not exceed stated dose.

Do not wash or shampoo dogs after treatment. Should you need to shampoo your dog, it is recommended to renew the application of Defendog afterwards in order to maintain protection against flea reinfestation.

4.4 Special warnings for each target species

FLAMMABLE. Keep treated animals away from fires and other sources of heat for at least 30 minutes following spraying and until the fur is totally dry. Do not spray on naked flame or any incandescent material.

If signs of disease persist or appear consult your veterinary surgeon or veterinary practitioner.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated with a suitable insecticide and vacuumed regularly. This will aid reduction in environmental challenge and maximise the duration of protection against re-infestation given by Defendog.

4.5 Special precautions for use

Special precautions for use in animals

Care should be taken to avoid spraying into the eyes of the animal.

This product is poisonous to cats. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Special Precautions to be taken by the Person Administering the Product to Animals

It is recommended to use household gloves when using the product.

Do not inhale spray mist. Use only in well ventilated areas.

Avoid contact with skin and eyes. Wash hands and exposed skin thoroughly after use.

Keep away from food and drink.

Avoid prolonged exposure.

Dangerous to bees.

Dangerous to fish and crustaceans.

Do not use spray in areas containing aquaria, fish tanks and bowls.

4.6 Adverse reactions (frequency and seriousness)

Very rare cases of nervous signs (tremors, ataxia, salivation, lethargy) and vomiting can be observed.

4.7 Use during pregnancy, lactation or lay

Do not use on nursing bitches.

Remove fleas from puppies and nursing bitches by careful use of a flea comb.

4.8 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.9 Amounts to be administered and administration route

50 ml of active solution per 10 kg bodyweight, equivalent to 100 mg permethrin per kg bodyweight. To achieve this dosage, the trigger pump should be activated approximately as follows:

Small dog (e.g. terrier)	1 to 10 kg	2 to 17 pump activations.
Medium dog (e.g. collie)	10 to 20 kg	17 to 34 pump activations.
Large dog (e.g. German shepherd)	20 to 30 kg	34 to 50 pump activations.

Apply Defendog against the lay of the hair and make sure that the entire coat of the animal is wetted. Ruffle the coat especially in long haired animals so that the product penetrates down to the skin. Allow the product to dry without wiping the coat. The quality of protection will be enhanced if the animal is already clean and dry.

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

Should signs of intolerance occur, shampoo the dog to eliminate the product.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Defendog is an insecticidal spray containing permethrin technical (40:60) as active ingredient. Permethrin, a synthetic pyrethroid, has a very rapid knock down activity on the peripheral nervous system of insects. It also has insect repellent properties.

Defendog contains a film forming agent which coats and protects the surface of the skin and fur, providing an extended residual activity.

It seems that pyrethroids act by blocking the transmission of nerve impulses in insects. Those effects are attributed to variations in the timing and amount of Na⁺ and K⁺ ions crossing the axonic membranes during the potential of action.

5.2 Pharmacokinetic properties

Permethrin is persistent on the animal's fur for the duration of the activity of Defendog.

Defendog is active for 42 days against fleas in dogs depending on the environmental challenge.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Luviset CAP
Methyl-ethyl propylene glycol
Jasmine perfume A1969
Purified Water

6.2 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

Do not store above 30°C. Protect from light.

Once the trigger pump is fitted store the container upright.

6.5 Nature and composition of immediate packaging

Defendog is supplied in an opaque high density polyethylene bottle with a high density polyethylene screw fit cap and a dosing device – metering pump (model 7600 – alfa corporation) delivering approximately 3 ml of product per activation. The container sizes are 250 ml and 500 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not contaminate ponds, waterways or ditches with the product or empty container.

Dangerous to bees. Dangerous to fish and crustaceans. Do not contaminate aquaria, fish tanks/bowls, etc. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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L.I.D.
06516 Carros Cedex
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/53/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th June 1997

Date of last renewal: 12th June 2007

10 DATE OF REVISION OF THE TEXT

March 2015