SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DUOWIN, Cutaneous Spray, Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For 100 ml :
Active substances :
Permethrin (Cis:Trans 40:60) ..... 1.88 g
Pyriproxyfen..... 20 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.
Clear and pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use,specifying the target species

Treatment and prevention of flea (*Ctenocephalides felis*) and tick (*Rhipicephalus sanguineus, Ixodes ricinus*) infestations.

Against fleas:
Treatment and prevention of a new infestation by adult fleas for 6 weeks.
Prevention of flea multiplication for 10 weeks by sterilizing the eggs.

Against ticks:
Treatment and prevention of a new infestation for 4 weeks.

4.3 Contraindications

Do not use on cats as adverse reactions and even death can occur.
See also sections 4.5. and 4.7.

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.
Underdosing should be avoided in order to maintain the claimed duration of efficacy.
Care should be taken to accurately weigh the animal and to comply with the recommended number of activations of the pump as DUOWIN is being applied.

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 DUOWIN.

4.5 Special precautions for use

i/ Special precautions for use in animals

Do not use on puppies under 2 months of age.
Do not use on sick or convalescent dogs.
Do not use on cats as adverse reactions and even death can occur.
Prevent treated animals from licking or grooming themselves, and in multianimal households prevent
other animals from grooming treated dogs, at least until the coat is dry.
This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats who are unable to metabolise the amount of permethrin contained in Duowin Spray. Symptoms are severe ; seizures and ataxia which can result in cat death.
To prevent accidental contact with Duowin Spray keep cats away from treated dogs until hair coat is dry. It is important to ensure that cats do not lick off the solution from treated dogs.
Life-threatening poisoning may occur. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. In case of exposure of this type, seek veterinary advice immediately if this occurs.

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

Use impervious household gloves (e.g.: rubber neoprene or vinyl) when using the product.
Do not spray on naked flame or any incandescent material.
FLAMMABLE.
Do not smoke, drink or eat while handling 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.
In case of accidental eye contact, flush eyes abundantly with water.
Keep away from food or drink.
Avoid prolonged exposure.

iii/ Other precautions

Do not allow dogs to enter ponds or streams on the day they have been treated.

4.6 Adverse reactions (frequency and seriousness)

Rare cases of pruritus, gastrointestinal signs or behavioural changes (agitation or apathy), have been observed which disappear rapidly without treatment.
In very rare occasions, dogs may show neurological symptoms such as tremors and hypersalivation.

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

Do not use on nursing bitches.
Consult your veterinary surgeon for appropriate treatment of flea and tick infestations in puppies and nursing bitches.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use any other ectoparasiticide in conjunction with Duowin.

4.9 Amounts to be administered and administration route

For external use only.
One pump activation delivers approximately 3.0 ml.
The dosage is 5 ml of solution per kg bodyweight which can be achieved by 5 pump activations for 3 kg bodyweight.
This is equivalent to 94 mg Permethrin and 1 mg Pyriproxyfen per kg bodyweight.

Weight of dog	*3 kg*	*7 kg*	*10 kg*	*15 kg*	*20 kg*	*30 kg*	*40 kg*
Number of pump activations	*5*	*12*	*17*	*25*	*34*	*50*	*67*

Spray onto the animal haircoat (avoiding the eyes) in order to wet it entirely. While spraying, ruffle the coat and apply against the lay of the hair so that the product penetrates down to the skin. Care should be taken to avoid spraying into the eyes of the animal. Allow the product to dry naturally without wiping the coat.

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

Dogs which have been repeatedly exposed to heavy rain or which enter water frequently should be retreated.

The product is a Prescription Only Medicine which can be used according to parasite pressure.
Retreatment may be advised at monthly intervals in case of strong flea infestation.

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

A tolerance study performed on puppies from 2 months of age at 5 times the recommended dosage showed no adverse reactions. However, should signs of intolerance occur (hyperaesthesia, ataxia, erythema, tremors), shampoo the dog thoroughly and repeatedly in order to eliminate the product.
In case of more severe signs of poisoning (convulsions), immediate symptomatic treatment should be undertaken under veterinary surveillance. No specific antidote to permethrin is known, however neurological symptoms should be treated e.g. with atropine and anti-convulsivant agents.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides
ATC code: QP53AC54
The product is presented as an insecticidal and acaricidal solution for topical use, containing an association of an adulticidal active ingredient, Permethrin, and an ovicidal and larvicidal active ingredient, Pyriproxyfen.

5.1 Pharmacodynamic properties

Permethrin is a synthetic pyrethroid which rapidly kills fleas and ticks by inducing repetitive nerve discharges leading to eventual paralysis of parasites. Those effects are attributed to variations in time and amount of Na+ and K+ ions crossing the axonic membranes during the potential of action. In addition to the killing effect, permethrin also exerts a rapid knock-down effect. It has also repellent properties on insects, which facilitate the flushing of the fleas from treated areas.

Pyriproxyfen is an insect growth inhibitor. It prevents the development of eggs and larvae thus preventing the establishment of new adult fleas.

The product contains an organic copolymer which facilitates the attachment of the active ingredients.

5.2 Pharmacokinetic particulars

The product is for topical use only and permethrin and pyriproxifen have limited absorption through the skin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Luviset CAN
Jasmine perfume E-96711
Methylether of propylene glycol

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

Store the container upright.

6.5 Nature and composition of immediate packaging

250 or 500 ml bottles made of high density polyethylene stopped with screw stoppers made of high density polyethylene.
Mechanical spraying device made of polypropylene.
Carton box.

Carton box containing one 250 ml polyethylene bottle and one mechanical spraying device;
Carton box containing one 500 ml polyethylene bottle and one mechanical spraying device.

Carton box containing one 250 ml polyethylene bottle fitted with one mechanical spraying device.
Carton box containing one 500 ml polyethylene bottle fitted with one mechanical spraying device.
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

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

Do not contaminate waterways or ditches with the product or empty containers

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue – L.I.D. - 2065m
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4046

9. DATE OF FIRST AUTHORISATION

24 July 1997

10 DATE OF REVISION OF THE TEXT

October 2017

Approved: 25 October 2017