ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box : 250 ml or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duowin, Cutaneous spray, Solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

For 100 ml :
Active substance<s>:

Permethrin (Cis:Trans 40:60)	1.88	g
Pyriproxyfen.....	20	mg

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.

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

8. SPECIAL WARNING(S), IF NECESSARY

Do not use on cats as adverse reactions and even death can occur.
Do not use on puppies under 2 months of age.
Do not use on sick or convalescent dogs.
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.
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.

See package leaflet for special precautions to be taken by the person administering the veterinary medicinal product to animals

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10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Store the container upright.
Keep the bottle in the outer carton

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 05653/4046

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 250 ml
Bottle of 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duowin, Cutaneous spray, Solution.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

For 100 ml :

Permethrin (Cis:Trans 40:60)	1.88	g
Pyriproxyfen.....	20	mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

250ml.
500 ml.

4. TARGET SPECIES

Dogs.

5. ROUTE(S) OF ADMINISTRATION

For external use only.

6. WARNINGS

Do not use on cats.
FLAMMABLE.

7. SPECIAL STORAGE PRECAUTIONS

Store the container upright.
Keep the bottle in the outer carton.

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4046

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

10. BATCH NUMBER

<Batch> <Lot> <BN> {number}

11. EXPIRY DATE

EXP {month/year}

12. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Duowin Cutaneous Spray Solution

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer for the batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duowin Cutaneous Spray Solution.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

For 100 ml :
Active substances :

Permethrin (Cis:Trans 40:60)	1.88	g
Pyriproxyfen.....	20	mg

Excipients:
Luviset CAN, Jasmine perfume E-96711, methylether of propylene glycol, purified water.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use on cats as adverse reactions and even death can occur.
Do not use on puppies under 2 months of age.
Do not use on sick or convalescent dogs.
Do not use on nursing bitches.
Consult your veterinary surgeon for appropriate treatment of flea and tick infestations in puppies and nursing bitches.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. SPECIAL STORAGE PRECAUTIONS

Store the container upright.
Keep the bottle in the outer carton
Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the label and carton after EXP.

11. WITHDRAWAL PERIOD

Not applicable.

12. SPECIAL WARNING(S)

Special precautions for use in animals

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.
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.
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.
Do not use any other ectoparasiticide in conjunction with Duowin.
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.
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.
Do not allow dogs to enter ponds or streams on the day they have been treated.

Special precautions for the person administering the veterinary medicinal product

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

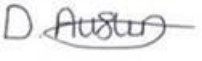
Dangerous to fish and crustaceans.
Do not use spray in areas containing aquaria, fish tanks and bowls.

Do not contaminate waterways or ditches with the product or empty containers. Unused product must not be washed down the drain.
Containers must not be rinsed.

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

14. OTHER INFORMATION

Presentations :
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.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Approved: 25 October 2017