ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer cardboard carton, pack size of 1, 2, 3, 4, 6 and 24 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

REFORDOG 40 mg/200 mg spot-on solution for dogs over 1.5 kg up to 4 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette of 0.4 ml contains:

Active substance:

Imidacloprid:	40.0 mg
Permethrin:	200.0 mg

3. PACKAGE SIZE

1 x 0.4 ml
2 x 0.4 ml
3 x 0.4 ml
4 x 0.4 ml
6 x 0.4 ml
24 x 0.4 ml

4. TARGET SPECIES

Dogs (over 1.5 kg up to 4 kg).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use. For external use only.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

In order to prevent children from getting access to pipettes, keep the pipette(s) in the original packaging.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetpharma

14. MARKETING AUTHORISATION NUMBERS

GB – Vm 32509/5000
NI – Vm 32509/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON POUCHES

Aluminium pouch - international version (no translation required) – Product inside pouches

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

REFORDOG

1.5 kg - 4 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.4 ml:

Imidacloprid 40.0 mg
Permethrin 200.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Vet pharma

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette - international version (no translation required)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

REFORDOG

1.5 kg - 4 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.4 ml:

Imidacloprid 40.0 mg
Permethrin 200.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

REFORDOG 40 mg/200 mg spot-on solution for dogs over 1.5 kg up to 4 kg
REFORDOG 100 mg/500 mg spot-on solution for dogs over 4 kg up to 10 kg
REFORDOG 250 mg/1250 mg spot-on solution for dogs over 10 kg up to 25 kg
REFORDOG 400 mg/2000 mg spot-on solution for dogs over 25 kg up to 40 kg
REFORDOG 600 mg/3000 mg spot-on solution for dogs over 40 kg up to 60 kg

2. Composition

Each pipette contains:

Name of the veterinary medicinal product	Pipette size	Active substances		Excipients	
		Imidacloprid	Permethrin	Butylhydroxytoluene	N-Methylpyrrolidone
REFORDOG for dogs over 1.5 kg up to 4 kg	0.40 ml	40.0 mg	200.0 mg	0.4 mg	193 mg
REFORDOG for dogs over 4 kg up to 10 kg	1.0 ml	100.0 mg	500.0 mg	1.0 mg	482 mg
REFORDOG for dogs over 10 kg up to 25 kg	2.5 ml	250.0 mg	1250.0 mg	2.5 mg	1206 mg
REFORDOG for dogs over 25 kg up to 40 kg	4.0 ml	400.0 mg	2000.0 mg	4.0 mg	1929 mg
REFORDOG for dogs over 40 kg up to 60 kg	6.0 ml	600.0 mg	3000.0 mg	6.0 mg	2893 mg

Pale yellow clear liquid

3. Target species

Dogs.

4. Indications for use

For dogs with, or at risk from mixed infestations by fleas, biting lice, ticks, sand flies, mosquitos and stable flies. The veterinary medicinal product is only indicated when use against all the following parasite species is required at the same time.

For the treatment and prevention of flea (*Ctenocephalides canis, Ctenocephalides felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The veterinary medicinal product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the veterinary medicinal product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the veterinary medicinal product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore, the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to the veterinary medicinal product's activity against the vector.

5. Contraindications

In the absence of available data, the veterinary medicinal product should not be used on puppies of less than 7 weeks of age or dogs of 1.5 kg of weight or less.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use on cats. (Refer to section 6 – Other precautions).

6. Special warnings

Special warnings for each target species:

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

Resistance to permethrin has been reported in fleas, ticks (*Rhipicephalus sanguineus*), in stable flies (*Stomoxys calcitrans*), mosquitoes (*Culex pipiens, Aedes aegypti*) and Sandflies (*P. papatasi*).

The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.
In the absence of risk of co-infestation, a narrow spectrum product should be used.

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E.canis* from 3 days following application of the veterinary medicinal product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. Perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

The possibility that other animals in the same household can be a source of re-infection with fleas, ticks or biting lice should be considered, and these should be treated as necessary with an appropriate product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The veterinary medicinal product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure, the persistent efficacy may be reduced. In these cases, do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the veterinary medicinal product.

Special precautions for safe use in the target species:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the veterinary medicinal product correctly as described under section 9. In particular, oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Consult your veterinary surgeon before using the veterinary medicinal product on sick and debilitated dogs.

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

This veterinary medicinal product contains butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

Veterinary medicinal product for dogs over 10 kg up to 25 kg, veterinary medicinal product for dogs over 25 kg up to 40 kg, and veterinary medicinal product for dogs over 40 kg up to 60 kg: Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Avoid contact between the veterinary medicinal product and skin, eyes or mouth.
Do not eat, drink or smoke during application. Do not ingest.
Wash hands thoroughly after use. In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.
In case of accidental spillage onto skin, wash off immediately with soap and water.
People with known hypersensitivity to permethrin should avoid contact with the veterinary medicinal product.
If the veterinary medicinal product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists, obtain medical attention immediately and show the package insert to the physician.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Treated dogs must not be handled especially by children for at least 12 hours after application of the veterinary medicinal product. It is therefore recommended to treat the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

Special precautions for the protection of the environment:

Imidacloprid and permethrin containing products are toxic to honey bees.

As the veterinary medicinal product is dangerous for aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

Other precautions:

Do not use on cats.

This veterinary medicinal product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the veterinary medicinal 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 veterinary medicinal product. Seek veterinary advice immediately if this occurs.

The solvent in the spot-on veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation, or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the veterinary medicinal product.

7. Adverse events

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site itching, application site hair change (e.g. greasy fur). Vomiting.
Rare (1 to 10 animals / 10,000 animals treated):	Application site erythema, application site inflammation, application site hair loss. Diarrhoea.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Increased skin sensitivity (scratching, rubbing).[1,2] Lethargy.[2] Agitation[1,2,3], restlessness[1,2,3], whining[1,2,3], rolling.[1,2,3] Hypersalivation[1,2,3], decreased appetite.[1,2,3] Neurological disorder (e.g. abnormal movement, twitching).[1,2,3]

[1] transient
[2] self-resolving
[3] in dogs susceptible to permethrin

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological disorders such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Spot-on use. For external use only.

Underdosing could result in ineffective use and may favour resistance development.

The recommended minimum dose is:
10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

Dosing Scheme for the veterinary medicinal product:

Dogs (kg body weight)	**Volume (ml)**	**Content of imidacloprid / permethrin**	**Imidacloprid (mg/kg body weight)**	**Permethrin (mg/kg body weight)**
> 1.5 kg ≤ 4 kg	0.4 ml	40 mg/200 mg	10 - 26	50 - 133
> 4 kg ≤ 10 kg	1.0 ml	100 mg/500 mg	10 - 25	50 - 125

> 10 kg ≤ 25 kg	2.5 ml	250 mg/1250 mg	10 - 25	50 - 125
> 25 kg ≤ 40 kg	4.0 ml	400 mg/2000 mg	10 - 16	50 - 80
> 40 kg ≤ 60 kg	6.0 ml	600 mg/3000 mg	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

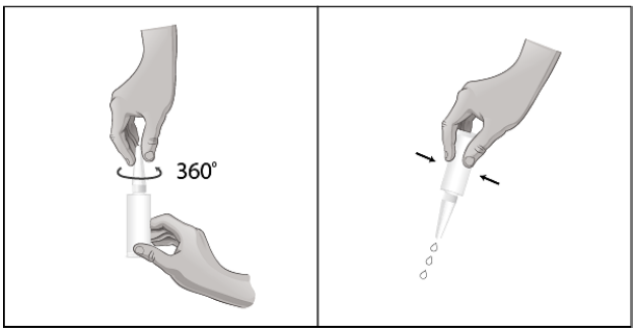
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

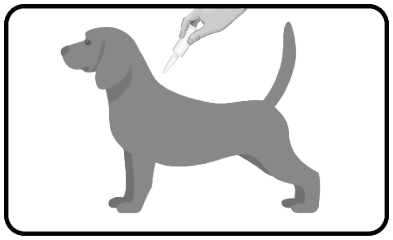
For infestations with fleas, ticks, mosquitos and stable flies, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

Method for administration

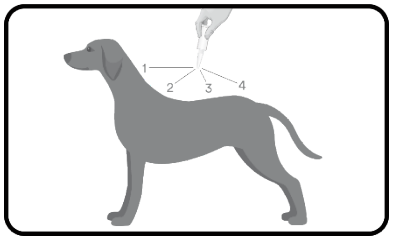
Remove one pipette from the package. Hold applicator pipette in an upright position for opening it. The cap should be rotated clockwise or counter clockwise one full turn. The cap will stay on the pipette; it is not possible to remove it. The pipette is open and ready for application. The entire content of the pipette has to be applied to the animal's skin.



Veterinary medicinal product for dogs over 1.5 kg up to 4 kg and veterinary medicinal product for dogs over 4 kg up to 10 kg:
With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



Veterinary medicinal product for dogs over 10 kg up to 25 kg, veterinary medicinal product for dogs over 25 kg up to 40 kg, and veterinary medicinal product for dogs over 40 kg up to 60 kg:
With the dog standing still, the entire contents of the pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. 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.



9. Advice on correct administration

For external use only. Apply only to undamaged skin. Animals should be weighed accurately prior to treatment. 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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
This veterinary medicinal product should not enter water courses as permethrin/imidacloprid may be dangerous for fish and other aquatic organisms.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

REFORDOG 40 mg/200 mg spot-on solution for dogs over 1.5 kg up to 4 kg
GB - Vm 32509/ 5000 / NI - Vm 32509/3000

REFORDOG 100 mg/500 mg spot-on solution for dogs over 4 kg up to 10 kg
GB - Vm 32509/5001 / NI - Vm 32509/3001

REFORDOG 250 mg/1250 mg spot-on solution for dogs over 10 kg up to 25 kg
GB - Vm 32509/5002 / NI - Vm 32509/3002

REFORDOG 400 mg/2000 mg spot-on solution for dogs over 25 kg up to 40 kg
GB - Vm 32509/5003 / NI - Vm 32509/3003

REFORDOG 600 mg/3000 mg spot-on solution for dogs over 40 kg up to 60 kg
GB - Vm 32509/5004 / NI - Vm 32509/3004

Type of container: White laminated PP/aluminium/PP single use pipette closed with a polyethylene cap.

Material of the secondary packaging: Pipette without pouch:
Cardboard tray to hold the pipette(es) and a cardboard box.

Pipette individually pouched:
PET/aluminium/PP three-layer pouch(es) in a cardboard box.

Pack sizes:
Cardboard box containing 1 pipette of 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml, or 6.0 ml with or without pouch.
Cardboard box containing 2 pipettes of 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml, or 6.0 ml with or without pouch.
Cardboard box containing 3 pipettes of 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml, or 6.0 ml with or without pouch.
Cardboard box containing 4 pipettes of 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml, or 6.0 ml with or without pouch.
Cardboard box containing 6 pipettes of 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml, or 6.0 ml with or without pouch.
Cardboard box containing 24 pipettes of 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml, or 6.0 ml with or without pouch.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for batch release:
AB7 Santé
Chemin des Monges
31450 Deyme
France

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 14 October 2024