PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PREVEXTO 4.50g + 2.03g medicated collar

2. STATEMENT OF ACTIVE SUBSTANCES

Each collar of 70 cm contains:
4.50 g imidacloprid
2.03 g flumethrin

3. PACKAGE SIZE

1 x collar
2 x collars

4. TARGET SPECIES

Dogs > 8 kg

5. INDICATIONS

Mixed infestation by fleas, ticks and lice. Only for use against the target pathogens at the same time.
Treatment of flea infestation and prevention of flea re-infestation for 7 to 8 months.
Prevention of re-infestation with ticks from 2 days to 8 months.
Reduction of the risk of babesiosis and ehrlichiosis for 7 months due to activity against the tick vector.
Treatment of lice infestations.

Ticks

Fleas

Larvae

Lice

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the sachet in the outer carton.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBER

Vm 05653/5078

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevexto medicated collar

2. STATEMENT OF ACTIVE SUBSTANCES

4.50 g Imidacloprid + 2.03 g Flumethrin per collar

3. TARGET SPECIES

> 8 kg

4. ROUTES OF ADMINISTRATION

Cutaneous use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Keep the sachet in the outer carton until use.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Prevexto 1.25 g + 0.56 g, medicated collar for dogs up to 8 kg
Prevexto 4.50 g + 2.03 g, medicated collar for dogs over 8 kg

2. Composition

Prevexto 1.25 g + 0.56 g, medicated collar for dogs up to 8 kg
Each collar of 38 cm (12.5 g) contains:

Active substances:
imidacloprid 1.25 g
flumethrin 0.56 g

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Titanium dioxide (E 171)	0.063 g
Black Iron Oxide (E 172)	0.010 g
Brown Iron Oxide (E 172)	0.005 g
Yellow Iron Oxide (E 172)	0.010 g

Light-grey collar with potential traces of white powder.

Prevexto 4.50 g + 2.03 g, medicated collar for dogs over 8 kg
Each 70 cm collar (45 g) contains:

Active substances:
imidacloprid 4.50 g
flumethrin 2.03 g

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Titanium dioxide (E 171)	0.225 g
Black Iron Oxide (E 172)	0.036 g
Brown Iron Oxide (E 172)	0.018 g
Yellow Iron Oxide (E 172)	0.036 g

Light-grey collar with potential traces of white powder.

3. Target species

Dogs

4. Indications for use

For dogs with or at risk from mixed infestation by fleas, ticks and lice targeted by each of the combined active substances. The veterinary medicinal product is only indicated when used against the target pathogens at the same time.

Treatment of flea infestation (*Ctenocephalides felis*) and prevention of flea re-infestation (*Ctenocephalides felis, C. canis*) due to insecticidal activity for 7 to 8 months.
Protects the animal's immediate surroundings against flea larvae development for 8 months.
The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinarian.

Prevention of re-infestation with ticks (*Ixodes ricinus, Rhipicephalus sanguineus*) through acaricidal (killing) effect and through repellent (anti-feeding) effect from 2 days to 8 months.
Prevention of re-infestation with ticks (*Dermacentor reticulatus*) through acaricidal (killing) effect from 2 days to 8 months.
It is effective against larvae, nymphs and adult ticks.

Reduction of the risk of transmission of the pathogens *Babesia canis vogeli* and *Ehrlichia canis* thereby reducing the risk of canine babesiosis and canine ehrlichiosis for 7 months through acaricidal and repellent effects on the tick vector *Rhipicephalus sanguineus*. The effect is indirect due to product's activity against the vector.

Treatment of infestation by biting/chewing lice (*Trichodectes canis*).

5. Contraindications

Do not treat puppies less than 7 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
Ticks already on the dog prior to treatment may not be killed within 48 hours after collar application and may remain attached and visible. Therefore removal of ticks already on the dog at the time of application is recommended. If you are unsure how to safely remove ticks from your animal, seek professional guidance. The prevention of infestations with new ticks starts within two days after application of the collar.

Ticks will be killed and fall off the host within 24 to 48 hours after infestation without having had a blood meal, as a rule. An attachment of single ticks after treatment cannot

be excluded. For this reason, a transmission of infectious diseases by ticks cannot be completely excluded if conditions are unfavourable.

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet 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.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

In the absence of risk of co-infestation by fleas, ticks and lice, a narrow spectrum product should be used.

Ideally, the collar should be applied before the beginning of the flea or tick season.

As in all long-term topical products, periods of excessive seasonal hair shedding may lead to transient slight reduction of efficacy by loss of hair-bound portions of the active ingredients. Replenishment from the collar starts immediately so that full efficacy will be re-established without any additional treatment or collar replacement.
For optimum control of flea problems in heavily infested households it may be necessary to treat the environment with a suitable insecticide.

Fleas can infest pets' beds, sleeping areas and usual resting areas like rugs and sofas. In the event of a massive infestation, these places should be treated with a suitable insecticide and vacuumed regularly.

The possibility that other animals in the same household can be a source of re-infestation with fleas, ticks or lice should be considered, and these should be treated as necessary with an appropriate product.

The veterinary medicinal product is water resistant; it remains effective if the animal becomes wet. However, shampooing or prolonged, intense exposure to water should be avoided as the duration of activity may be reduced.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental ingestion of the veterinary medicinal product can induce adverse effects, including neurotoxic effects.
Avoid oral exposure or accidental ingestion, especially by children.
Keep the sachet with the collar in the outer packaging until use and keep the collar in the sachet until use.
Do not allow small children to play with the collar, or to put it into their mouth.
Immediately dispose of any remnants or cut-offs of the collar (see section 8 "Dosage for each species, routes and method of administration").

In case of oral exposure or accidental ingestion, seek immediate medical advice and show the package leaflet or the label to the physician.

The veterinary medicinal product may cause hypersensitivity reactions in some people.
People with known hypersensitivity (allergy) to the ingredients of the collar, or iron oxide, should avoid contact with the veterinary medicinal product and the treated animal.
In case of hypersensitive reactions seek medical advice and show the package leaflet or the label to the physician.

The veterinary medicinal product may cause skin, eye and respiratory irritation in some people in very rare cases.
Avoid eye and skin contacts.
In case of eye irritation, flush eyes thoroughly with cold water.
In case of skin irritation, wash the skin with soap and cold water.
If symptoms persist it is recommended to seek medical advice and show the package leaflet or the label to the physician.
Imidacloprid and flumethrin are continuously released from the collar to the skin and fur whilst the collar is being worn.
Avoid prolonged contact with the collar when placing it on the animal and also when it is worn by the treated animal. This especially applies to pregnant women.

Wash hands with cold water after fitting the collar.
Pets wearing the collar should not be allowed to sleep in the same bed as their owners, especially children.

Special precautions for the protection of the environment:
Imidacloprid and flumethrin may adversely affect aquatic organisms. Dogs wearing the collar should not be allowed to swim in water courses.
Imidacloprid containing products are toxic to honey bees.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in target animals during pregnancy and lactation or in breeding animals.
The use is not recommended during pregnancy and lactation.
Laboratory studies with flumethrin in rats and rabbits have not produced teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

Laboratory studies with imidacloprid in rats and rabbits have not produced any evidence of teratogenic or foetotoxic effects.

Fertility:
Laboratory studies with either flumethrin or imidacloprid in rats and rabbits have not produced any effects on fertility or reproduction.

Interaction with other medicinal products and other forms of interaction:
None known.
Overdose:

Due to the nature of the collar overdose is unlikely and signs of overdose are not to be expected.
An overdose of 5 collars around the neck was investigated in adult dogs for an 8 month period and in 7 week old puppies for a 6 month period and no adverse effects were observed besides slight hair loss and mild skin reactions.
In the unlikely event of the animal eating the collar mild gastrointestinal symptoms (e.g. loose stool) may occur.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
None known.

7. Adverse events

Dogs

Rare (1 to 10 animals / 10,000 animals treated):	Application site reaction[1] (e.g. Erythema, Hair loss, Pruritus, Scratching) Behavioural disorder[2] (e.g. Excessive chewing, licking and grooming[3], Hiding, Hyperactivity, Vocalisation) Diarrhoea[4], Hypersalivation[4], Vomiting[4] Change in food intake[4] Depression[4] Neurological symptoms[5] (e.g. Ataxia, Convulsions, Tremor)
Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)	Application site reaction[5] (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion) Aggression[6]

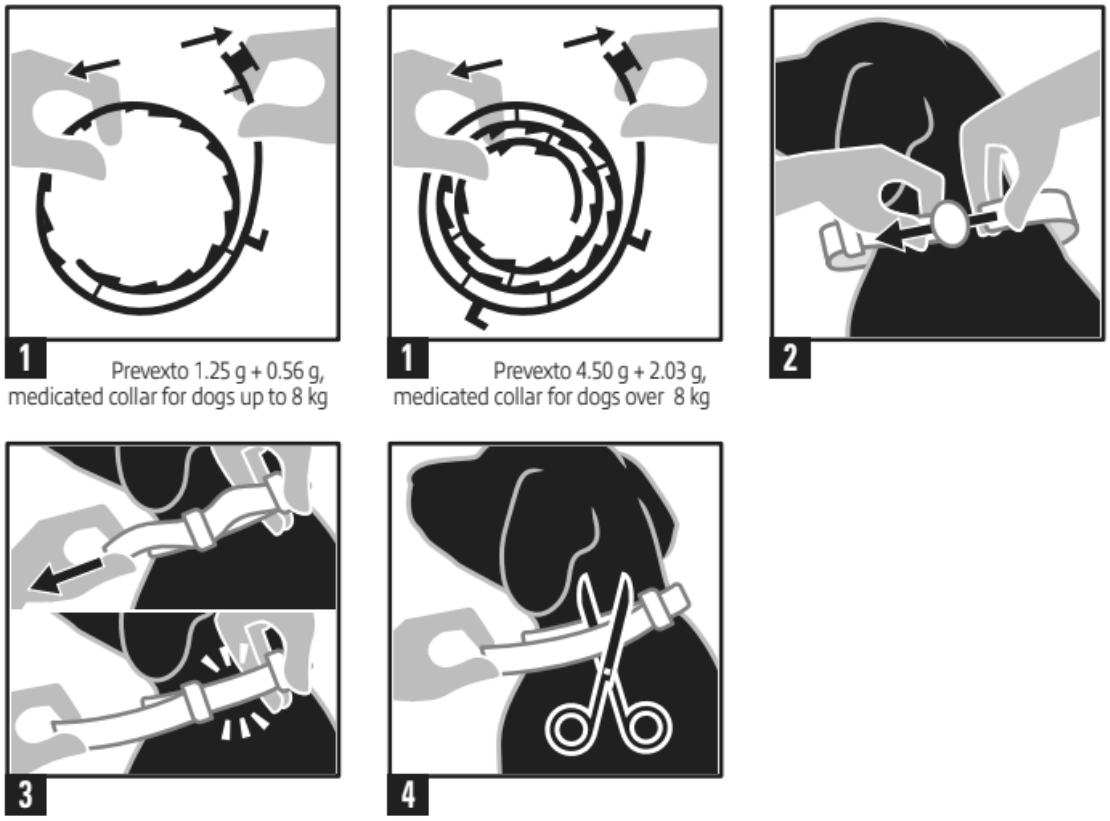
[1] Signs usually resolve within 1 to 2 weeks. In single cases, temporary collar removal is recommended until signs resolve. [2] May be observed in animals that are not used to wearing collars on the first few days after fitting.
[3] At the application site.
[4] Slight and transient reactions that might occur with initial use.
[5] In these cases, collar removal is recommended.
[6] Ensure that collar is fitted correctly.

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

Cutaneous use. One collar per animal to be fastened around the neck.
Small dogs up to 8 kg body weight receive one collar of 38 cm length.
Dogs above 8 kg receive one collar of 70 cm length.
For external use only.



1 Remove collar from protective sachet directly before use and apply immediately. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.
2 Adjust the collar around the animal's neck without tightening it too tight.
3 As a guide, it should be possible to insert 2 fingers between the collar and the neck.
4 Pull excess collar through the loop(s) and cut off any excess length extending beyond 2 cm. Immediately dispose of any remnants or cut-offs of the collar

Prevexto 1.25 g + 0.56 g, medicated collar for dogs up to 8 kg
This collar is designed with a safety-closure mechanism. In the extremely rare event of a dog being trapped, the animal’s own strength is usually sufficient to break the collar to allow for quick release.

The collar should be worn continuously for the 8 month protection period and should be removed after the treatment period. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.

9. Advice on correct administration

Not applicable

10. Withdrawal periods

Not Applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the sachet in the outer carton until use.

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.

The veterinary medicinal product should not enter water courses as imidacloprid and flumethrin 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 not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Prevexto 1.25 g + 0.56 g - Vm 05653/5077
Prevexto 4.50 g + 2.03 g - Vm 05653/5078

Carton box containing 1 or 2 collars

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:
VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

Manufacturer responsible for batch release:
AB7 santé
Chemin des Monges - BP9
31450 Deyme
France

Local representatives and contact details to report suspected adverse reactions:
Virbac Ltd,
Suffolk, IP30 9UP – UK
Tel: +44 (0)-1359 243243
enquiries@virbac.co.uk

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

17. Other information

NFA-VPS

Gavin Hall

Approved: 27 August 2025