

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevexto 1.25g + 0.56g medicated collar

2. STATEMENT OF ACTIVE SUBSTANCES

Each collar of 38 cm contains:
1.25 g imidacloprid
0.56 g flumethrin

3. PACKAGE SIZE

1 x collar
2 x collars

4. TARGET SPECIES

Cats



5. INDICATIONS

Mixed infestation by fleas and ticks. 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.

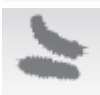
Prevention of re-infestation with ticks from 2 days to 8 months.



Ticks



Fleas



Larvae

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the sachet in the outer carton until use.

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 05653/3036

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevexto medicated collar

2. STATEMENT OF ACTIVE SUBSTANCES

1.25 g Imidacloprid + 0.56 g Flumethrin per collar

3. TARGET SPECIES



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}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Prevexto 1.25 g + 0.56 g, medicated collar for cats

2. Composition

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.

3. Target species



Cats.

4. Indications for use

For cats with or at risk from mixed infestation by fleas and ticks 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 and prevention of flea re-infestation (*Ctenocephalides felis*) due to insecticidal activity for 7 to 8 months.

Protects the animal's immediate surroundings against flea larvae development for 10 weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where it has been previously diagnosed by a veterinarian.

Prevention of re-infestation with ticks (*Ixodes ricinus*) through acaricidal (killing) effect and through repellent (anti-feeding) effect from 2 days to 8 months.

Prevention of re-infestation with ticks (*Rhipicephalus turanicus*) through acaricidal (killing) effect from 2 days to 8 months.

It is effective against larvae, nymphs and adult ticks.

5. Contraindications

Do not treat kittens less than 10 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 cat 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 cat 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 and ticks, 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 or ticks 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 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 oxides, 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.

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 cats for an 8 months period and in 10 week old kittens for a 6 months period and no other adverse effects were observed than already described in section 7 “adverse events”.

In the unlikely event of the animal eating the collar mild gastrointestinal symptoms (e.g. loose stool) may occur.

7. Adverse events

Cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site reaction ¹ (e.g. Erythema, Hair loss, Pruritus)
Rare (1 to 10 animals / 10,000 animals treated):	Application site reaction ² (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion, Scratching) Behavioural disorder ³ (e.g. Excessive chewing, licking and grooming ⁴ , Hiding, Hyperactivity, Vocalisation) Diarrhoea ⁵ , Hypersalivation ⁵ , Vomiting ⁵ Change in food intake ⁵ Depression ⁵
Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)	Aggression ⁶
Undetermined frequency	Contact dermatitis ⁷

¹ Signs usually resolve within 1 to 2 weeks. In single cases, temporary collar removal is recommended until signs resolve.

- ² Collar removal is recommended.
- ³ May be observed in animals that are not used to wearing collars on the first few days after fitting.
- ⁴ At the application site.
- ⁵ Slight and transient reactions that might occur with initial use.
- ⁶ Ensure that collar is fitted correctly
- ⁷ Noted in hypersensitive animals.

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:

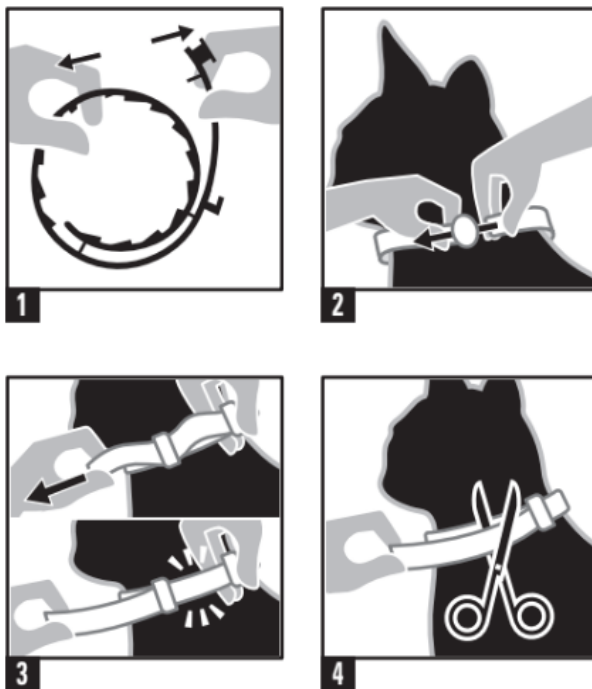
Website: <https://www.gov.uk/report-veterinarymedicine-problem/animal-reacts-medicine>
e-mail: adverse.events@vmd.gov.uk

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

Cutaneous use. One collar per animal to be fastened around the neck.

Cats receive one collar of 38 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 and cut off any excess length extending beyond 2 cm. Immediately dispose of any remnants or cut-offs of the collar.

This collar is designed with a safety-closure mechanism. In the very rare event of a cat 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 kittens are rapidly growing.

9. Advice on correct administration

Not applicable.

10. Withdrawal periods

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 sachet and carton 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 or household waste.

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

Vm 05653/3036

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
1^{ère} 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 events:

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

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