

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parecto 1.25 g + 0.56 g medicated collar for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 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
Polyvinyl chloride	
Dibutyl adipate	
Epoxidized soybean oil	
Stearic acid	
Titanium dioxide E171	0.04 g
Iron oxide black E172	0.02 g

Grey collar with potential traces of white powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cat

### 3.2 Indications for use for each target species

For cats with, or at risk from, mixed parasitic infestations by ticks and fleas. The veterinary medicinal product is only indicated when use against ticks and fleas is indicated at the same time.

Treatment and prevention of flea re infestations (*Ctenocephalides felis*) due to insecticidal activity for 5.5 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).

Prevention of re-infestation with ticks (*Ixodes ricinus*) through acaricidal (killing) effect from 9 days to 8 months and through repellent (anti-feeding) effect from 2 days to 8 months.

It is effective against larvae, nymphs and adult ticks.

### 3.3 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.

### **3.4 Special warnings**

Ticks already on the cat prior to treatment may not be killed within 9 days 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 2 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 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.

The use of the 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.

The efficacy of the collar against fleas is insufficient after 5,5 months of collar application. As a risk of development / emergence of resistance of fleas to imidacloprid cannot be excluded, a reasonable use after 5,5 months should be considered by the veterinarian and the pet owner. Beyond this period of 5,5 months, in case of continuing flea infestation, the collar should be removed and an adequate treatment may be necessary.

Pet fleas often infest their beds, sleeping areas and usual resting areas like rugs and sofas. In the event of a massive infestation, start of treatment, these places will 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 the activity may be reduced.

### **3.5 Special precautions for use**

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 ingestion, especially children. Keep the collar in the sachet until use. Keep the sachet with the collar in the outer packaging until use.

Do not allow small children to play with the collar, or to put it into their mouths.

Immediately dispose of any remnants or cut-offs of the collar (see section 3.9 and 5.5).

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

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.

Pets wearing the collar should not be allowed to sleep in the same bed as their owners, especially children.

Imidacloprid and Flumethrin are continuously released from the collar to the skin and fur whilst the collar is being worn.

The veterinary medicinal product may cause hypersensitivity reactions in some people.

People with known hypersensitivity (allergy) to imidacloprid and/or flumethrin 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.

Wash hands with cold water after handling the collar.

Special precautions for the protection of the environment:

The veterinary medicinal product should not enter water courses as imidacloprid and flumethrin may be dangerous for fish and other aquatic organisms.

Imidacloprid containing products are toxic to honey bees.

### 3.6 Adverse events

Cats

Uncommon (1 to 10 animals / 1000 animals treated):	Application site reaction <sup>1</sup> (e.g. Erythema, Hair loss, Pruritus)
Rare (1 to 10 animals / 10,000 animals treated):	Application site reaction <sup>2</sup> (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion, Scratching) Behavioural disorder <sup>3</sup> (e.g. Excessive chewing, licking and grooming <sup>4</sup> , Hiding, Hyperactivity, Vocalisation) Diarrhoea <sup>5</sup> , Hypersalivation <sup>5</sup> , Vomiting <sup>5</sup> Appetite disorder <sup>5</sup> , Depression <sup>5</sup>

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Aggression <sup>6</sup>
Undetermined frequency (cannot be estimated from the available data)	Contact dermatitis <sup>7</sup>

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

<sup>2</sup> Collar removal is recommended.

<sup>3</sup> May be observed in animals that are not used to wearing collars on the first few days after fitting.

<sup>4</sup> At the application site.

<sup>5</sup> Slight and transient reactions that might occur with initial use.

<sup>6</sup> Ensure that collar is fitted correctly.

<sup>7</sup> Noted in hypersensitive animals.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

#### Pregnancy and lactation:

The use is not recommended during pregnancy and lactation.

Laboratory studies with either flumethrin or 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.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

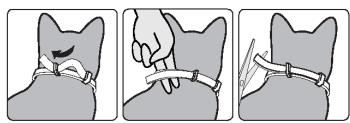
### 3.9 Administration routes and dosage

Cutaneous use.

One collar per animal to be fastened around the neck.

Cats wear one collar of 38 cm length.

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



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

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 widen the collar to allow for quick release.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

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 the adverse reaction section.

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

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QP53AC55

### **4.2 Pharmacodynamics**

Imidacloprid is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is active against larval flea stages, adult fleas and lice.

Imidacloprid has a high affinity for the nicotinic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) of the flea. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinic receptors and the postulated poor penetration through the blood-brain barrier in mammals, it has virtually no effect on the mammalian CNS. Imidacloprid has minimal pharmacological activity in mammals.

Flumethrin is an ectoparasiticide of the synthetic pyrethroid group. According to current knowledge the synthetic pyrethroids interfere with the sodium channel of nerve cell membranes, resulting in a delay in repolarization of the nerve and finally killing of the parasite. In studies on structure-activity relationship of a number of pyrethroids interference with receptors of a certain chiral conformation was noted thereby causing a selective activity on ectoparasites. No anti-cholinesterase activity was noted with these compounds. Flumethrin is responsible for the veterinary medicinal product's acaricidal activity and also prevents production of fertile eggs by its lethal effect on female ticks.

The veterinary medicinal product provides repellent (anti-feeding) activity against the claimed ticks, thus preventing repelled parasites from taking a blood meal.

### **4.3 Pharmacokinetics**

Both active ingredients are slowly and continuously released in low concentrations from the polymer matrix system of the collar towards the animal. Both actives are present in the cat's haircoat in acaricidal/insecticidal concentrations during the entire efficacy period. The active substances spread from the site of direct contact over the entire skin surface. Target animal overdose and serum kinetic

studies have established that imidacloprid reached the systemic circulation transiently while flumethrin was mostly not measurable.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Not applicable.

### **5.2 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

### **5.3 Special precautions for storage**

Store in the original package.

This veterinary medicinal product does not require any special temperature storage conditions. Keep the sachet with the collar in the outer box until use.

### **5.4 Nature and composition of immediate packaging**

38 cm polyvinyl chloride-based collar(s) individually packed in surlyn/aluminium/PE/PET sachet.

Carton box containing 1, 2 or 12 sachets.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

The veterinary medicinal product should not enter water courses as imidacloprid and flumethrin may be dangerous for fish and other aquatic organisms.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Beaphar B.V.

## **7. MARKETING AUTHORISATION NUMBER(S)**

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD/MM/YYYY}

## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{MM/YYYY}

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription (BE).

Veterinary medicinal product not subject to prescription (AT, BG, CY, CZ, DE, EL, ES, FI, FR, HR, HU, IT, MT, NL, PL, PT, RO, SI).

Veterinary medicinal product subject to prescription except for some pack sizes (FI, SE).

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box or carton pack**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Parecto 1.25 g + 0.56 g medicated collar

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each medicated collar contains: 1.25 g Imidacloprid, 0.56 g Flumethrin.

**3. PACKAGE SIZE**

1 x 38 cm collar

2 x 38 cm collar

12 x 38 cm collar

**4. TARGET SPECIES**



*[Front side:]*

*[Back side:]* Cats over 10 weeks of age

**5. INDICATIONS**

*[Front side:]*

Kills and repels ticks for 8 months.

Kills fleas and flea larvae.

*Pictograms tick, flea, flea larvae*

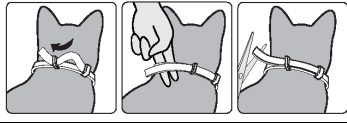
*[Back side:]*

- For the treatment and prevention of flea infestations for 5.5 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).
- For the prevention of re-infestations of ticks for 8 months.
- It is effective against larvae, nymphs and adult ticks.

Use only in case of (a risk for) mixed infestations by fleas and ticks at the same time.

**6. ROUTES OF ADMINISTRATION**

Cutaneous use.



Safety-closure mechanism.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Keep the sachet with the collar in the outer box 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**

Beaphar B.V.

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGING UNITS**

**Surlyn/alu/PE/PET sachet**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Parecto

**2. QUANTITATIVE PARTICULARS OF ACTIVE SUBSTANCES**

1.25 g Imidacloprid, 0.56 g Flumethrin.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Parecto 1.25 g + 0.56 g medicated collar for cats

### 2. Composition

One 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
Polyvinyl chloride	
Dibutyl adipate	
Epoxidized soybean oil	
Stearic acid	
Titanium dioxide E171	0.04 g
Iron oxide black E172	0.02 g

Grey collar with potential traces of white powder.

### 3. Target species

Cat



### 4. Indications for use

For cats that have, or may be at risk of, combined infestations with ticks and fleas. This product should only be used when protection against ticks and fleas is needed at the same time.

Treatment and prevention of flea re infestations (*Ctenocephalides felis*) due to insecticidal (i.e. killing) activity for 5.5 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).

Prevention of re-infestation with ticks (*Ixodes ricinus*) for 8 months. The acaricidal (killing) effect starts at 9 days and the repellent (anti-feeding) effect at 2 days

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 9 days 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 the 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.

The efficacy of the collar against fleas is insufficient after 5,5 months of collar application. As a risk of development / emergence of resistance of fleas to imidacloprid cannot be excluded, a reasonable use after 5,5 months should be considered by the veterinarian and the pet owner. Beyond this period of 5,5 months, in case of continuing flea infestation, the collar should be removed and an adequate treatment may be necessary.

Pet fleas often infest their beds, sleeping areas and usual resting areas like rugs and sofas. In the event of a massive infestation, start of treatment, these places will 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 the 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 ingestion, especially children. Keep the collar in the sachet until use. Keep the sachet with the collar in the outer packaging until use.

Do not allow small children to play with the collar, or to put it into their mouths.

Immediately dispose of any remnants or cut-offs of the collar (see section Advice on correct administration).

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

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.

Pets wearing the collar should not be allowed to sleep in the same bed as their owners, especially children.

Imidacloprid and Flumethrin are continuously released from the collar to the skin and fur whilst the collar is being worn.

The veterinary medicinal product may cause hypersensitivity reactions in some people.

People with known hypersensitivity (allergy) to imidacloprid and/or flumethrin 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.

Wash hands with cold water after handling the collar.

Special precautions for the protection of the environment:

This veterinary medicinal product should not enter water courses as imidacloprid and flumethrin may be dangerous for fish and other aquatic organisms.

Imidacloprid containing products are toxic to honey bees.

Pregnancy, lactation and fertility:

The use is not recommended during pregnancy and lactation.

The safety of the veterinary medicinal product has not been established in cats during pregnancy and lactation.

Laboratory studies with either flumethrin or imidacloprid have not shown 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 medicated collar overdose is unlikely and signs of overdose are not to be expected.

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

Major incompatibilities:

None known.

**7. Adverse events**

Cats:

<b>Uncommon (1 to 10 animals / 1000 animals treated):</b>
Application site reaction <sup>1</sup> (e.g. Erythema (redness), Hair loss, Pruritus (itching))
<b>Rare (1 to 10 animals / 10 000 animals treated):</b>
Application site reaction <sup>2</sup> (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion, Scratching) Behavioural disorder <sup>3</sup> (e.g. Excessive chewing, licking and grooming <sup>4</sup> Hiding, Hyperactivity, Vocalisation) Diarrhoea <sup>5</sup> , Hypersalivation <sup>5</sup> (increased salivation), Vomiting <sup>5</sup> Appetite disorder <sup>5</sup> , Depression <sup>5</sup>
<b>Very rare (&lt; 1 animal / 10 000 animals treated, including isolated reports):</b>
Aggression <sup>6</sup>
<b>Undetermined frequency (cannot be estimated from the available data):</b>
Contact dermatitis <sup>7</sup>

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

<sup>2</sup> Collar removal is recommended.

<sup>3</sup> May be observed in animals that are not used to wearing collars on the first few days after fitting.

<sup>4</sup> At the application site.

<sup>5</sup> Slight and transient reactions that might occur with initial use.

<sup>6</sup> Ensure that collar is fitted correctly.

<sup>7</sup> 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {insert national system details}.

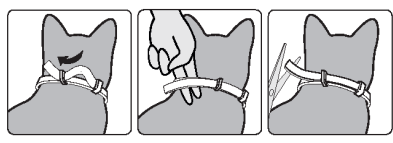
**8. Dosage for each species, routes and method of administration**

Cutaneous use. Cats wear one collar of 38 cm length.

One collar per animal to be fastened around the neck. For external use only.

**9. Advice on correct administration**

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



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

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 widen the collar to allow for quick release.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Store in the original package.

This veterinary medicinal product does not require any special temperature storage conditions. Keep the sachet with the collar in the outer box until use.

Do not use after expiry date stated on the sachet and outer box. 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.

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.

The veterinary medicinal product should not enter water courses as imidacloprid and flumethrin may be dangerous for fish and other aquatic organisms.

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 (BE).

Veterinary medicinal product not subject to prescription (AT, BG, CY, CZ, DE, EL, ES, FI, FR, HR, HU, IT, MT, NL, PL, PT, RO, SI).

Veterinary medicinal product subject to prescription except for some pack sizes (FI, SE).

#### **14. Marketing authorisation numbers and pack sizes**

{MA-number}:

Carton box containing 1, 2 or 12 sachets, each containing one collar.

Not all pack sizes may be marketed.

**15. Date on which the package leaflet was last revised**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**16. Contact details**

Marketing authorisation holder

Beaphar B.V.  
Drostenkamp 3  
8101 BX Raalte  
The Netherlands

Manufacturer responsible for batch release:

Beaphar B.V.  
Oude Linderteseweg 9  
8102 EV Raalte  
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

*{Names and addresses to be completed during the national phase.}*

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

**17. Other information**

Both active ingredients are slowly and continuously released in low concentrations from the polymer matrix system of the medicated collar towards the animal. Both actives are present in the cat's haircoat in acaricidal/insecticidal concentrations during the entire efficacy period. The active substances spread from the site of direct contact over the entire skin surface. Target animal overdose and serum kinetic studies have established that imidacloprid reached the systemic circulation transiently while flumethrin was mostly not measurable. Oral absorption of both active substances is not relevant for the clinical efficacy.

The veterinary medicinal product provides repellent (anti-feeding) activity against the claimed ticks, thus preventing repelled parasites from taking a blood meal and thereby indirectly aids in the reduction of the risk of Vector-Borne Disease transmission.