

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

No common name.

National names:

FR: DELTAPLUS BIOCANINA 1,04 G COLLIER MEDICAMENTEUX POUR GRANDS CHIENS

PT: REMU-VET 1.04 g Coleira antiparasitária para Cães grandes

ES: REMU-VET 1.04 g collar medicamentoso para Perros Grandes

IT: REMU-VET 1.04 g collare antiparassitario per Cani di taglia grande

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 65 cm collar (26 g) contains:

**Active substance :** Deltamethrin 1.04 g

**Excipient s:**

<Qualitative composition of excipients and other constituents>
Carbon black
Epoxidized soybean oil
Diisonyl adipate
Triphenyl phosphate
Polyvinyl chloride
Calcium stearate
Zinc stearate
Stearic acid

Black medicated collar, which releases a white powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dog

### 3.2 Indications for use

The veterinary medicinal product provides:

- Prevention of fleas re-infestation with *Ctenocephalides felis* through an insecticidal effect for 16 weeks;
- Prevention of tick re-infestation with *Ixodes ricinus* through an acaricidal effect for 6 months;
- Prevention of bites by sandflies (*Phlebotomus perniciosus*) through an insecticidal and anti-feeding effect for 5.5 months.

### 3.3 Contraindications

Do not use in puppies less than 7 weeks of age.

Do not use on dogs with skin lesions.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use on cats. Deltamethrin is harmful to cats.

### 3.4 Special warnings

As the collar exerts its full effect against *Ctenocephalides felis*, *Ixodes ricinus*, and *Phlebotomus perniciosus* after one week, the collar should preferably be applied 1 week before animals are likely to become exposed to infestation.”

*Ixodes ricinus* ticks and *Phlebotomus perniciosus* sandflies will be killed and fall off the host within 48 and 24 hours after exposure, respectively, without having had a blood meal, as a rule. An attachment of single ticks or bite of single sandflies after treatment cannot be excluded. For this reason, transmission of infectious diseases by ticks or sandflies cannot be completely excluded if conditions are unfavourable.

For optimal control of flea infestations in multi-pet households, all dogs in the household should be treated at the same time.

Fleas from pets often infest the animal's basket, bedding and regular resting areas, such as carpets and soft furnishings. These should be treated in cases of massive infestation and upon the initiation of control measures with a suitable insecticide, and vacuumed regularly.

The influence of shampooing or an immersion on the duration of efficacy has not been investigated. Occasional contact with water does not reduce the effectiveness of the collar.

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 dog.

Resistance to pyrethroids and in particular to deltamethrin has been reported in fleas (*C. felis*) and in ticks (*Rhipicephalus sanguineus*) in dogs. The use of this product should take into account local information about susceptibility of the target parasites, where available.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of skin lesions, remove the collar until symptoms have resolved.

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

Accidental ingestion of this product may cause adverse reactions, including neurotoxic effects. Keep the product in the original carton. Keep the collar in the sachet until use. Do not smoke, eat or drink while handling the collar. Do not allow children to play with the collar or to put it into their mouths. Immediately dispose of any remnants or cut-offs of the collar. Wash hands with cold water after fitting the collar.

Avoid prolonged contact with the collar or dog wearing the collar. This includes sharing a bed with dogs wearing the collar; this is particularly important for children.

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

Deltamethrin may cause hypersensitivity (allergic) reactions in sensitive people. People with known hypersensitivity to deltamethrin should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hypersensitivity reactions.

Special precautions for the protection of the environment:

Deltamethrin is toxic for aquatic organisms. Dogs wearing the collar are not allowed to enter watercourses.

### 3.6 Adverse events

#### Dogs

<i>Rare</i> (1 to 10 animals / 10,000 animals treated):	<i>Application site pruritus, erythema, hair loss</i>
<i>Very rare</i> (<1 animal / 10,000 animals treated, including isolated reports):	<i>Lethargy, hyperactivity, ataxia, muscle tremor, vomiting, diarrhoea, hypersalivation</i>

If any of these symptoms occur, the collar should be removed and contact with a veterinarian is advised.

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, its local representative, or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Laboratory studies have not produced any evidence of developmental or embryotoxic effect. However, the safety of the veterinary medicinal product has not been established in pregnant dogs. Therefore, the product should be used during pregnancy and lactation only according to the benefit/risk assessment by the responsible veterinarian.

#### Pregnancy and lactation:

Use only according to the benefit/risk assessment by the responsible veterinarian. Laboratory studies have not produced any evidence of a teratogenic or embryotoxic effect.

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

Do not use with other ectoparasiticides (pyrethroids, organophosphates).

### 3.9 Administration routes and dosage

Cutaneous use. One collar per dog is to be fastened around the neck. Remove the collar from the protective sachet right before use. Fit the collar around the animal's neck neither too loose nor too tight: two fingers side-by-side should fit between the collar and the dog's neck. Cut off any excess length extending beyond 5 cm. Check periodically and adjust the fit easily by applying pressure on top of the buckle and then sliding the collar into the correct position.



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

In the unlikely event of the dog eating the collar, the following symptoms may occur: Uncoordinated movements, tremor, drooling of saliva, vomiting, rigidity of the hindquarters. These symptoms usually subside within 48 hours.

For more information concerning symptomatic treatment it is advised to contact your

local veterinarian.

### **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: QP53AC11.**

### **4.2 Pharmacodynamics**

Deltamethrin is an ectoparasiticide of the pyrethroid class. Insects and acarines are exposed to deltamethrin through contact. The mechanism of action is based on a sustained increase in the sodium permeability of the insect's nerve membranes. This results in hyperactivity followed by paralysis (shock effect), tremor and death of the parasite.

### **4.3 Pharmacokinetics**

Deltamethrin is slowly and continuously released from the collar into the dogs' coat. The active substance spreads from the site of direct contact over the entire skin surface through the lipids and in the hair. Deltamethrin is not absorbed systemically by the host.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Not applicable.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 60 months

Shelf life after first opening of the sachet: use immediately

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

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

Keep the sachet(s) in the outer carton

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

Material of the primary packaging:

PET/PE/aluminium/surlyn sachet containing one collar.

Pack sizes:

Cardboard box containing 1 or 2 child resistant sachets.

Not all pack sizes may be marketed.

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

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

The veterinary medicinal product should not enter water courses as deltamethrin 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 national collection systems applicable to the veterinary medicinal product concerned.

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

Beaphar B.V.

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

XXXXXXXXXX

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD month 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 not subject to prescription.

ES, FR, IT, PT

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

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

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE  
CARDBOARD BOX**

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

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ES: REMU-VET 1.04 g collar medicamentoso para Perros Grandes

IT: REMU-VET 1.04 g collare antiparassitario per Cani di taglia grande

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 26 g collar contains:

Deltamethrin ..... 1.04 g

**3. PACKAGE SIZE**

1 collar

2 collars

**4. TARGET SPECIES**

Large dogs

**5. INDICATIONS**

The veterinary medicinal product provides:

- Prevention of fleas re-infestation with *Ctenocephalides felis* through an insecticidal effect for 16 weeks;
- Prevention of tick re-infestation with *Ixodes ricinus* through an acaricidal effect for 6 months;
- Prevention of bites by sandflies (*Phlebotomus perniciosus*) through an insecticidal and anti-feeding effect for 5.5 months.

**6. ROUTES OF ADMINISTRATION**

For cutaneous use only.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

This veterinary medicinal product does not require any special temperature storage conditions.  
Keep the sachet(s) in the outer carton.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Beaphar B.V.

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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XXXXXXXXXX

<b>15. BATCH NUMBER</b>
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Lot {number}

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

**Sachet**

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

*No common name.*

*National names:*

*FR: COLLIER DELTAPLUS BIOCANINA*

*PT: REMU-VET 1.04 g Coleira*

*ES: REMU-VET 1.04 g collar*

*IT: REMU-VET 1.04 g collare*



1 x 65cm

**beaphar**

Optional logo

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Deltamethrin 1.04 g

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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IT: REMU-VET 1.04 g collare antiparassitario per Cani di taglia grande

### 2. Composition

Each 65 cm collar (26 g) contains:

Active substance : Deltamethrin 1.04 g

Black medicated collar, which releases a white powder.

### 3. Target species

Dogs

### 4. Indications for use

The veterinary medicinal product provides:

- Prevention of fleas re-infestation with *Ctenocephalides felis* through an insecticidal effect for 16 weeks;
- Prevention of tick re-infestation with *Ixodes ricinus* through an acaricidal effect for 6 months;
- Prevention of bites by sandflies (*Phlebotomus perniciosus*) through an insecticidal and anti-feeding effect for 5.5 months

### 5. Contraindications

Do not use in puppies less than 7 weeks of age.

Do not use on dogs with skin damage.

Do not use in case of hypersensitivity (allergy) to the active substance or to any of the excipients.

Do not use on cats. Deltamethrin is harmful to cats.

### 6. Special warnings

As the collar exerts its full effect against *Ctenocephalides felis*, *Ixodes ricinus*, and *Phlebotomus perniciosus* after one week, the collar should preferably be applied 1 week before animals are likely to become exposed to infestation.”

*Ixodes ricinus* ticks and *Phlebotomus perniciosus* sandflies will be killed and fall off the host within 48 and 24 hours after exposure, respectively, without having had a blood meal, as a rule. An attachment of single ticks or bite of single sandflies after treatment cannot be excluded. For this reason, transmission of infectious diseases by ticks or sandflies cannot be completely excluded if conditions are unfavourable.

For optimal control of flea infestations in multi-pet households, all dogs in the household should be treated at the same time.

Fleas from pets often infest the animal's basket, bedding and regular resting areas, such as carpets and soft furnishings. These should be treated in cases of massive infestation and upon the initiation of control measures with a suitable insecticide, and vacuumed regularly.

The influence of shampooing or an immersion on the duration of efficacy has not been investigated. Occasional contact with water does not reduce the effectiveness of the collar.

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 dog.

Resistance to pyrethroids and in particular to deltamethrin has been reported in fleas (*C. felis*) and in ticks (*Rhipicephalus sanguineus*) in dogs. The use of this product should take into account local information about susceptibility of the target parasites, where available.

Special precautions for safe use in the target species:

In case of skin lesions, remove the collar until symptoms have resolved.

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

Accidental ingestion of this product may cause adverse reactions, including neurotoxic effects. Keep the product in the original carton. Keep the collar in the sachet until use. Do not smoke, eat or drink while handling the collar. Do not allow children to play with the collar or to put it into their mouths. Immediately dispose of any remnants or cut-offs of the collar. Wash hands with cold water after fitting the collar.

Avoid prolonged contact with the collar or dog wearing the collar. This includes sharing a bed with dogs wearing the collar; this is particularly important for children.

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

Deltamethrin may cause hypersensitivity (allergic) reactions in sensitive people. People with known hypersensitivity to deltamethrin should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hypersensitivity reactions.

Special precautions for the protection of the environment:

Deltamethrin is toxic for aquatic organisms. Dogs wearing the collar are not allowed to enter watercourses.

Pregnancy and lactation:

Use only according to the benefit/risk assessment by the responsible veterinarian. Laboratory studies have not produced any evidence of a teratogenic or embryotoxic effect.

Interactions with other medicinal products and other forms of interaction:

Do not use with other ectoparasiticides containing organophosphates.

Overdose:

In the unlikely event of the dog eating the collar, the following symptoms may occur: Uncoordinated movements, tremor, drooling of saliva, vomiting, rigidity of the hindquarters. These symptoms usually subside within 48 hours. For more information concerning symptomatic treatment it is advised to contact your local veterinarian.

Major incompatibilities:

Not applicable.

**7. Adverse events**

Dogs

Rare	Application site pruritus, erythema, hair loss
------	--

(1 to 10 animals / 10,000 animals treated):	
Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	<i>Lethargy, hyperactivity, ataxia, muscle tremor, vomiting, diarrhoea, hypersalivation</i>

If any of these symptoms occur, the collar should be removed and contact with a veterinarian is advised.

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, its local representative, or the national competent authority via the national reporting system. See also section 16 of this package leaflet for respective contact details.

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

For cutaneous use only. One collar per dog is to be fastened around the neck.

## **9. Advice on correct administration**



Remove the collar from the protective sachet right before use. Fit the collar around the animal's neck neither too loose nor too tight: two fingers side-by-side should fit between the collar and the dog's neck. Cut off any excess length extending beyond 5 cm. Check periodically and adjust the fit easily by applying pressure on top of the buckle and then sliding the collar into the correct position.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Keep the sachet(s) in the outer carton

Shelf life after first opening of the immediate packaging: use immediately.

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 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.

This veterinary medicinal product should not enter water courses as deltamethrin 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

ES, FR, IT, PT

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

XXXXXX

Pack sizes:

Cardboard box containing 1 or 2 child resistant sachets

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>).

### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release

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

Marketing authorisation holder and contact details to report suspected adverse reactions:

Local representatives 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.

#### **France**

{Nom}

<{Adresse}

FR-00000 {Localité}>

Tél: + {Numéro de téléphone}

<{E-mail}>

#### **Italia**

{Nome}

<{Indirizzo}

IT-00000 {Località}>

Tel: + {Numero di telefono}>

<{E-mail}>

#### **España**

{Nombre}

<{Dirección}

ES-00000 {Ciudad}>

Tel: + {Teléfono}

<{E-mail}>

#### **Portugal**

{Nome}

<{Morada}

PT-0000-000 {Cidade}>

Tel: + {Número de telefone}

<{E-mail}>



**17. Other information**