

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combote 50 mg/60 mg spot-on solution for cats & ferrets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette (0.5 ml) contains:

Active substances:

Fipronil 50 mg
(S)-Methoprene 60 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg
Ethanol 96%	
Polysorbate 80	
Polyvidone K17	
Diethylene glycol monoethyl ether	

Clear amber spot-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats and ferrets.

3.2 Indications for use for each target species

In cats:

- To be used against infestations with fleas, alone or in association with ticks and/or biting lice.
- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvical activity) originating from eggs laid by adult fleas for six weeks after application.
- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The veterinary medicinal product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Elimination of biting lice (*Felicola subrostratus*).

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

In ferrets:

- To be used against infestations with fleas, alone or in association with ticks.

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicultural activity) originating from eggs laid by adult fleas.
- Elimination of ticks (*Ixodes ricinus*). The veterinary medicinal product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

3.3 Contraindications

In the absence of available data, the veterinary medicinal product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg.

The veterinary medicinal product should not be used on ferrets less than 6 months old.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use on rabbits, as adverse drug reactions with even mortality could occur. In absence of studies, the use of the veterinary medicinal product is not recommended in non-target species.

Do not use in case of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Other animals living in the same household should also be treated with a suitable product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid the contact with the animal's eyes.

It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

No data on the effect of bathing/shampooing on the efficacy of the veterinary medicinal product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the veterinary medicinal product, it is not recommended to bathe animals within 2 days after application of the veterinary medicinal product.

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

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

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

This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Avoid contact of the veterinary medicinal product with mouth, skin and eyes. Wash hands after use. In case of accidental contact with the skin or eyes, rinse thoroughly with water. If irritation persists, seek medical advice.

This veterinary medicinal product may cause allergic reactions. People with known hypersensitivity to fipronil and/or (S)-methoprene should not treat their animal with this veterinary medicinal product.

This veterinary medicinal product may cause neurotoxicity and be harmful if swallowed. Avoid ingestion including hand-to-mouth contact. Do not smoke, drink or eat during application. Keep the pipettes in the original packaging until ready for use and dispose of used pipettes immediately. Wash hands after use. In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children

Special precautions for the protection of the environment:

See section 5.5

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

3.6 Adverse events

Cats and ferrets:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Application site skin scaling ¹ , Application site hair loss ¹ , Application site itching ¹ , Application site reddening ¹ , Generalised itching or hair loss Hypersalivation ² ; Vomiting Increased sensitivity to stimulation ³ , Central nervous system depression ³ , Neurological signs (NOS) ²
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¹ Transient

² If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

³ Reversible

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

Pregnancy and lactation:

Cats:

Can be used during pregnancy.

The potential toxicity of the veterinary medicinal product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

Ferrets:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spot-on use.

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

Cats:

One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, for cats weighing less than 10 kg.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

Ferrets:

One pipette of 0.5 mL per ferret corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret.

The minimum treatment interval is 4 weeks.

Method of administration:

Use the easy-peel corners to remove a pipette from its blister. Do not puncture the foil with scissors, knives or other sharp instruments, as this may damage the pipette inside.

Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Cut off the top of the pipette with scissors.

Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin.



Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal product since this will cause a transient sticky appearance of hairs at the treatment spot.

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

Do not overdose.

The risk of experiencing adverse effects may increase with overdosing (see section 3.6).

In cats:

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

In ferrets:

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

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 :

QP53AX65

4.2 Pharmacodynamics

The veterinary medicinal product is an insecticidal and acaricidal solution for topical use, containing an association of an adulticidal active ingredient, fipronil, in combination with an ovicidal and larvicidal active ingredient, (S)-methoprene.

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. Fipronil kills fleas within 24 hours, ticks (*Dermacentor variabilis*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Ixodes ricinus*, *Haemaphysalis longicornis*, *Haemaphysalis flava*, *Haemaphysalis campanulata*) and lice within 48 hours post-exposure.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of treated animals with the immature stages of fleas.

4.3 Pharmacokinetics

Studies of metabolism of fipronil have demonstrated that the major metabolite is the sulfone derivative of fipronil.

(S)-methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.

The pharmacokinetic profiles after topical application of fipronil and (S)-methoprene in combination were studied in cats in comparison to intravenous dosing of fipronil or (S)-methoprene alone. This established absorption and other pharmacokinetic parameters under conditions mimicking clinical practice. The topical application, with additional potential oral exposure from licking, resulted in overall systemic absorption of fipronil (18%) with a mean maximum concentration (C_{max}) of approximately 100 ng/ml fipronil and 13 ng/ml of fipronil sulfone in plasma. Peak fipronil plasma concentrations are rapidly attained (mean t_{max} approximately 6 h) and decline with a mean terminal half-life of approximately 25 h. Fipronil is slightly metabolised to fipronil sulfone in cats.

Plasma concentrations of (S)-methoprene were generally below the limit of quantitation (20 ng/ml) in cats after topical application.

Both (S)-methoprene and fipronil, together with its major metabolite, are well-distributed in the haircoat of cats within one day after application. The concentrations of fipronil, fipronil sulfone and (S)-methoprene in the hair coat decrease with time and are detectable for at least 59 days after dosing. Parasites are killed through contact rather than by systemic exposure.

No pharmacological interaction between fipronil and (S)-methoprene was noted.

The pharmacokinetic profile of the veterinary medicinal product has not been investigated in ferrets.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

Nature of primary packaging: A blue pipette is composed of a heat-formed shell (polypropylene/cyclic olefin copolymer/ethylene-vinyl alcohol copolymer/polypropylene) and a film (polyethylene terephthalate/aluminium/polypropylene).

The blue pipette is enclosed in an aluminium blister (polyethylene/polyamide/aluminium/polyamide/polyethylene and polyamide/aluminium/polyethylene).

Package sizes:

Cardboard box containing 1 aluminium blister with 1 pipette.

Cardboard box containing 1 aluminium blister with 2 pipettes.

Cardboard box containing 1 aluminium blister with 3 pipettes.

Cardboard box containing 1 aluminium blister with 4 pipettes.

Cardboard box containing 1 aluminium blister with 6 pipettes.

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.

The veterinary medicinal product should not enter water courses as Fipronil and (S)-methoprene 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)

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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 II
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combote 50 mg/60 mg spot-on

2. STATEMENT OF ACTIVE SUBSTANCES

Fipronil 50 mg
(S)-Methoprene 60 mg

3. PACKAGE SIZE

1 x 0.50 ml
2 x 0.50 ml
3 x 0.50 ml
4 x 0.50 ml
6 x 0.50 ml

4. TARGET SPECIES

Cats
Ferrets



5. INDICATIONS

Protects against infestations with fleas, alone or in combination with ticks and/or biting lice

- Kills fleas (*Ctenocephalides* spp.) and protects against new infestation in cats and ferrets during 4 weeks.
- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) and protects against new infestation in cats during 2 weeks and in ferrets during 4 weeks.
- Kills biting lice (*Felicola subrostratus*) in cats.
- Inhibits development of eggs, larvae and pupae of fleas (during 6 weeks in cats) and prevents infestation of the environment of the treated animal with premature fleas during the same period.
- The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) in cats.

Fipronil kills fleas within 24 hours and ticks and lice within 48 hours after treatment.

Optional (to print on front side of the box):

- Prevents infestation in the environment of the treated animal with premature fleas
- Kills fleas, ticks and biting lice

6. ROUTES OF ADMINISTRATION

Spot-on

Use one pipet to treat one cat or ferret. External use only. The minimum treatment interval is 4 weeks.



Do not use on cats less than 8 weeks old or weighing less than 1 kg
Do not use on ferrets less than 6 months old.

Cats: can be used during pregnancy. For usage during lactation, read the package leaflet.
Ferrets: For usage during pregnancy and lactation, read the package leaflet.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.
Do not use after the expiry date stated on the package.

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}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

ALU foil (blister)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combote^c

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 50 mg
(S)-Methoprene 60 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PP pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combote^c

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 50 mg
(S)-Methoprene 60 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Combotec 50 mg/60 mg spot-on solution for cats and ferrets

2. Composition

Each pipette (0.5 ml) contains:

Fipronil	50 mg
(S)-Methoprene	60 mg
Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg

Clear amber spot-on solution

3. Target species

Cats



Ferrets



4. Indications for use

Cats:

Protects against infestations with fleas, alone or in combination with ticks and/or biting lice.

- Kills fleas (*Ctenocephalides* spp.) and protects against new infestation in cats and ferrets during 4 weeks.
- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) and protects against new infestation in cats during 2 weeks and in ferrets during 4 weeks.
- Kills biting lice (*Felicola subrostratus*) in cats.
- Inhibits development of eggs, larvae and pupae of fleas (during 6 weeks in cats) and prevents infestation of the environment of the treated animal with premature fleas during the same period.
- The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) in cats.

Fipronil kills fleas within 24 hours and ticks and lice within 48 hours after treatment.

Ferrets:

Protects against infestations with fleas, alone or in combination with ticks and/or biting lice

- Kills fleas (*Ctenocephalides* spp.) and protects against new infestation in cats and ferrets during 4 weeks.
- Kills ticks (*Ixodes ricinus*) and protects against new infestation in cats during 2 weeks and in ferrets during 4 weeks.

5. Contraindications

In the absence of available data, the veterinary medicinal product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg.

The veterinary medicinal product should not be used on ferrets less than 6 months old.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use on rabbits, as serious reactions, including death, could occur. In absence of studies, the use of the veterinary medicinal product is not recommended in non-target species.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Avoid the contact with the animal's eyes.

It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment. No data on the effect of bathing/shampooing on the efficacy of the veterinary medicinal product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the veterinary medicinal product, it is not recommended to bathe animals within 2 days after application of the veterinary medicinal product.

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

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

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

This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Avoid contact of the veterinary medicinal product with mouth, skin and eyes. Wash hands after use. In case of accidental contact with the skin or eyes, rinse thoroughly with water. If irritation persists, seek medical advice.

This veterinary medicinal product may cause allergic reactions. People with known hypersensitivity to fipronil and/or (S)-methoprene should not treat their animal with this veterinary medicinal product.

This veterinary medicinal product may cause neurotoxicity and may be harmful if swallowed. Avoid ingestion including hand-to-mouth contact. Do not smoke, drink or eat during application. Keep the pipettes in the original packaging until ready for use and dispose of used pipettes immediately. Wash hands after use. In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

Special precautions for the protection of the environment:

See section on special precautions for disposal.

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

Pregnancy and lactation:

Cats:

The veterinary medicinal product can be used during pregnancy.

The potential toxicity of the veterinary medicinal product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

Ferrets:

The safety of the veterinary medicinal product has not been established in ferrets during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:

Do not overdose.

The risk of experiencing adverse effects may increase with overdosing.

In cats:

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

In ferrets:

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

Special restrictions for use and special conditions for use:

Other animals living in the same household should also be treated with a suitable veterinary medicinal product.

7. Adverse events

Cats and ferrets:

Very rare

(<1 animal / 10 000 animals treated, including isolated reports):

Application site skin scaling¹, Application site hair loss¹, Application site itching¹, Application site reddening¹. Generalised itching or hair loss. Hypersalivation²; Vomiting; Increased sensitivity to stimulation³, Central nervous system depression³, Neurological signs (NOS)²

¹ Transient

² If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

³ Reversible

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: {national system details}

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

Spot-on use, by topical application to the skin.

One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin, for cats weighing less than 10 kg.

One pipette of 0.5 ml per ferret, corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret, by topical application to the skin.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

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

9. Advice on correct administration

Use the easy-peel corners to remove a pipette from its blister. Do not puncture the foil with scissors, knives or other sharp instruments, as this may damage the pipette inside.



Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Cut off the top of the pipette with scissors.

Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin.



Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal product since this will cause a transient sticky appearance of hairs at the treatment spot

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. 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 Fipronil and (S)-methoprene 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

Cardboard box containing 1 aluminium blister with 1 pipette.

Cardboard box containing 1 aluminium blister with 2 pipettes.

Cardboard box containing 1 aluminium blister with 3 pipettes.
Cardboard box containing 1 aluminium blister with 4 pipettes.
Cardboard box containing 1 aluminium blister with 6 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month 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 events:

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

België/Belgique/Belgien

{Nom/Naam/Name}
{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}
Tél/Tel: + {N° de téléphone/Telefoonnummer/
Telefonnummer}
<{E-mail}>

Lietuva

{pavadinimas}
{adresas}
LT {pašto indeksas} {miestas}
Tel: + {telefono numeris}
<{E-mail}>

Република България

{Наименование}
{Адрес}
BG {Град} {Пощенски код}
Тел: + {Телефонен номер}
<{E-mail}>

Luxembourg/Luxemburg

{Nom}
{Adresse}
L-0000 {Localité/Stadt}
Tél/Tel: + {N° de téléphone/Telefoonnummer}
<{E-mail}>

Česká republika

{Název}
{Adresa}
CZ {město}
Tel: +{telefoniční číslo}
<{E-mail}>

Danmark

{Navn}
{Adresse}
DK-0000 {by}
Tlf.: + {Telefonnummer}
<{E-mail}>

Deutschland

{Name}
{Anschrift}
DE-00000 {Stadt}
Tel: + {Telefonnummer}
<{E-mail}>

Eesti

(Nimi)
(Aadress)
EE - (Postindeks) (Linn)
Tel: +(Telefoninumber)
<{E-mail}>

Ελλάδα

{Όνομα}
{Διεύθυνση}
EL-000 00 {πόλη}
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

España

{Nombre}
{Dirección}
ES-00000 {Ciudad}
Tel: + {Teléfono}
<{E-mail}>

France

{Nom}
{Adresse}
FR-00000 {Localité}
Tél: + {Numéro de téléphone}
<{E-mail}>

Hrvatska

{Ime}
{Adresa}
{Poštanski broj} {grad}
Tel: + {Telefonski broj}
<{e-mail}>

Magyarország

{Név}
{Cím}
HU-0000 {Város}
Tel.: + {Telefonszám}
<{E-mail}>

Malta

{Isem}
{Indirizz}
MT-0000 {Belt/Rahal}
Tel: + {Numru tat-telefon}
<{E-mail}>

Nederland

{Naam}
{Adres}
NL-0000 XX {stad}
Tel: + {Telefoonnummer}
<{E-mail}>

Norge

{Navn}
{Adresse}
N-0000 {poststed}
Tlf: + {Telefonnummer}
<{E-mail}>

Österreich

{Name}
{Anschrift}
A-00000 {Stadt}
Tel: + {Telefonnummer}
<{E-mail}>

Polska

{Nazwa/ Nazwisko:}
{Adres:}
PL – 00 000 {Miasto:}
Tel.: + {Numer telefonu:}
<{E-mail}>

Portugal

{Nome}
{Morada}
PT-0000-000 {Cidade}
Tel: + {Número de telefone}
<{E-mail}>

România

{Nume}
{Adresa}
{Oraș} {Cod poștal} – RO
Tel: + {Număr de telefon}
<{E-mail}>

Ireland

{Name}
{Address}
{Town} {Postal code} - IE
Tel: + {Telephone number}
<{E-mail}>

Ísland

{Nafn}
{Heimilisfang}
IS-000 {Borg/Bær}
Sími: + {Símanúmer}
<{Netfang}>

Italia

{Nome}
{Indirizzo}
IT-00000 {Località}
Tel: + {Numero di telefono}
<{E-mail}>

Κύπρος

{Όνομα}
{Διεύθυνση}
CY-000 00 {πόλη}
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Latvija

{Nosaukums}
{Adrese}
{Pilsēta}, LV {Pasta indekss }
Tel: + {Telefona numurs}
<{E-mail}>

Slovenija

{Ime}
{Naslov}
SI-0000 {Mesto}
Tel: + {telefonska številka}
<{E-mail}>

Slovenská republika

{Meno}
{Adresa}
SK-000 00 {Mesto}
Tel: + {Telefónne číslo}
<{E-mail}>

Suomi/Finland

{Nimi/Namn}
{Osoite/Adress}
FI-00000 {Postitoimipaikka/Stad}
Puh/Tel: + {Puhelinnumero/Telefonnummer}
<{E-mail}>

Sverige

{Namn}
{Adress}
SE-000 00 {Stad}
Tel: + {Telefonnummer}
<{E-mail}>

United Kingdom (Northern Ireland)

{Name}
{Address}
{Town} {Postal code} – UK
Tel: + {Telephone number}
<{E-mail}>>

17. Other information