

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prac-tic 56.25 mg spot-on solution for very small dogs

Prac-tic 137.5 mg spot-on solution for small dogs

Prac-tic 275 mg spot-on solution for medium dogs

Prac-tic 625 mg spot-on solution for large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Pyriprole 125 mg

One pipette delivers:

| | Unit dose | Pyriprole |
|------------------------------|-----------|-----------|
| Prac-tic for very small dogs | 0.45 ml | 56.25 mg |
| Prac-tic for small dogs | 1.1 ml | 137.5 mg |
| Prac-tic for medium dogs | 2.2 ml | 275 mg |
| Prac-tic for large dogs | 5.0 ml | 625 mg |

Excipients:

0.1% Butylhydroxytoluene (E321)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Colourless to yellow, clear spot-on solution for external application

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

Treatment and prevention of flea infestation (*Ctenocephalides canis* and *C. felis*) in dogs. Efficacy against new infestations with fleas persists for a minimum of 4 weeks.

Treatment and prevention of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Dermacentor reticulatus*, *Dermacentor variabilis*, *Amblyomma americanum*) in dogs. Efficacy against ticks persists for 4 weeks.

4.3 Contraindications

Do not use in dogs less than 8 weeks of age or with a body weight of less than 2 kg.

Do not use in cases of known hypersensitivity to phenylpyrazole class compounds or to any of the excipients.

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

This veterinary medicinal product is specifically developed for dogs.

Do not use in cats, as this could lead to overdosing.

Do not use in rabbits.

4.4 Special warnings for each target species

This veterinary medicinal product is for the treatment of ticks and adult fleas. All dogs in a household should be treated.

In cases of heavy infestation prior to treatment, the dog's surrounding should be vacuumed and treated with a suitable insecticide.

Dogs should not be bathed or shampooed from 48 hours before treatment. Immersion of the animal in water or shampooing within 24 hours after treatment may reduce the efficacy of the veterinary medicinal product. However, weekly immersion in water did not affect efficacy against fleas and ticks.

4.5 Special precautions for use

Special precautions for use in animals

Apply only to the skin surface and on intact skin.

This veterinary medicinal product is for external topical application as a spot-on treatment only. Do not administer orally or via any other route.

The dogs should be accurately weighed before the treatment.

Care should be taken to avoid contact of the veterinary medicinal product with the eyes of the animal.

It is important to apply the dose to an area where the dog cannot lick it off and to make sure that animals do not lick each other following treatment.

Following treatment, ticks will detach from the host within 24 to 48 hours after infestation; however, single ticks might remain on the animal. For this reason, a transmission of infectious diseases by ticks cannot be completely excluded.

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

As a precautionary measure, people should avoid contact with the treated area of the animals and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended to treat animals in the evening. Recently treated animals should not be allowed to sleep in the same bed as their owners, especially children.

People with known hypersensitivity to the phenylpyrazole class compounds or any of the excipients should avoid contact with the veterinary medicinal product.

Avoid skin contact with the pipette content. Wash hands or other exposed body parts after use with soap and water. If accidental eye exposure occurs, the eyes should be rinsed carefully with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the doctor. Do not smoke, eat or drink during application.

In case of contact with the product, numbness and irritation of skin and mucosa, which usually resolves spontaneously, may occur.

Other precautions

Care should be taken to avoid excessive wetting of the dog's hair with the veterinary medicinal product since this may cause a sticky and tangled appearance of hair at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

The solvent in Prac-tic may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions the following have been reported:

- application site and skin reactions: pruritus (itchy skin), hair change, dermatitis (inflammation of the skin), erythema (redness of skin), alopecia (loss of hair), fur discoloration and greasy appearance of hair.
- neurological reactions: ataxia (lack of coordination) and convulsions.
- systemic reactions: lethargy (drowsiness).
- digestive tract reactions: emesis (vomiting) and diarrhoea.

These signs are usually transient and disappear within 24 hours of the application; if they take longer to disappear consult your veterinarian.

A brief period of hypersalivation (drooling) may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within minutes without treatment. Correct application will minimise licking of the application site.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in pregnant or lactating bitches, nor in breeding animals, although in laboratory animal studies no indications of relevant effects on reproduction or foetal development were observed.

Do not use during pregnancy or lactation or consult a veterinary surgeon to establish the benefit/risk assessment of treatment during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known. However, dog owners are advised to consult a veterinary surgeon if they intend to use the product on dogs given other products/medication

4.9 Amounts to be administered and administration route

Spot-on use for external application.

Dosage Table

The recommended minimum dose is 12.5 mg pyriprole per kg bodyweight, equivalent to 0.1 ml spot-on solution per kg bodyweight.

| Weight range of dog | Pipette size to be used | One pipette of 12.5 % (w/v) solution contains (ml) | Pyriprole (mg/ kg bw) |
|---------------------|---|--|-----------------------|
| 2 – 4.5 kg | Very small dog | 0.45 | 12.5 – 28.1 |
| > 4.5 – 11 kg | Small dog | 1.1 | 12.5 – 30.6 |
| > 11 – 22 kg | Medium dog | 2.2 | 12.5 – 25.0 |
| >22 – 50 kg | Large dog | 5.0 | 12.5 – 28.4 |
| Greater than 50 kg | Use the appropriate combination of pipettes to achieve the correct dose | | |

Within each weight range the entire contents of the correct size pipette should be deposited on the dog's skin.

Flea treatment and prevention

Pyriprole kills fleas within 24 hours after application. One application prevents flea infestation for 4 weeks.

Tick treatment and prevention

Pyriprole kills ticks within 48 hours after application. One application is effective against ticks for 4 weeks.

Method of administration

For application to the skin only.

Remove one pipette from the package. Hold it in an upright position. Tap the narrow part of the pipette to ensure the contents are in the main body of the pipette. Snap-off the top of the pipette along the scored line.

Part the coat on the back of the animal between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze it gently several times at one or two spots to empty the contents onto the skin. Ensure the product is deposited on the skin. Apply the 5 ml pipette to 2-3 spots down the backline of large dogs in order to prevent run-off.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Mild neurological signs such as slight incoordination and unsteadiness were observed in some animals treated once a month at **3 times** the recommended maximum dose for six consecutive months. Those signs disappeared within 3 hours following administration.

In one out of 8 dogs repeatedly treated with **5 times** the recommended dose, the following transient adverse effects were observed: tremors (shaking), ataxia (lack of coordination), panting and convulsions. These signs disappeared within 18 hours following administration.

Following an overdose of 10 times the maximum dose on a single occasion the following adverse effects were seen: vomiting, anorexia (loss of appetite), reduced body weight, muscle tremors, seizures, unsteadiness, laboured breathing. All signs resolved within 48 hours, with the exception of the loss of appetite.

An overdose of the veterinary medicinal product may cause a sticky and tangled appearance of hair at the treatment spot for up to 24 hours.

In case of an overdose contact your veterinary surgeon.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use; ATCvet code: QP53AX26

5.1 Pharmacodynamic properties

The veterinary medicinal product is an insecticidal and acaricidal solution for spot-on use, containing pyriprole as active substance.

Pyriprole is an insecticide and acaricide belonging to the phenylpyrazole class. 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 fleas and ticks. In dogs, adverse reactions are associated with neurological signs caused by metabolites of the active substance.

Parasites are killed through contact rather than by systemic exposure. Pyriprole kills fleas within 24 hours and ticks (*Ixodes ricinus*, *Rhipicephalus sanguineus*, *Dermacentor reticulatus*, *Ixodes scapularis*, *Dermacentor variabilis*, *Amblyomma americanum*) within 48 hours post-exposure.

Adult fleas are killed before they lay eggs for a minimum of 4 weeks after treatment. Since the veterinary medicinal product completely eliminates egg production, it breaks the flea life cycle.

5.2 Pharmacokinetic particulars

In dogs, after administration to the skin pyriprole is slowly absorbed by skin, leading to a systemic exposure by its two main metabolites.

Following administration to the skin pyriprole is rapidly distributed in the hair coat of dogs within one day after application. It can be found in the hair coat throughout the treatment interval.

Environmental properties

Pyriprole may be harmful to aquatic organisms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Diethylene glycol monoethyl ether

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

6.4. Special precautions for storage

Store the pipettes in the original container in order to protect from light.

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

The spot on pipette is composed of a bright yellow polypropylene shell, with a pale yellow aluminium foil back coated with a polyethylene terephthalate film. The pipette is contained in a child resistant soft tempered aluminium foil/PVC blister.

Cardboard carton containing 1, 2 or 10 blisters each containing 3 pipettes.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Prac-tic should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/066/001-012

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 December 2006

Date of last renewal: 16 November 2011

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Elanco France S.A.S.
26, Rue de la Chapelle
68330 Huningue
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product not subject to prescription

C. STATEMENT OF THE MRLs

Not applicable.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The marketing authorisation holder shall submit a periodic update report (PSUR) every year for the next three years, followed by a two-yearly report; thereafter the reports shall be submitted at three-yearly intervals.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**CARDBOARD CARTON 56.25 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic 56.25 mg spot-on solution for very small dogs

2. STATEMENT OF ACTIVE SUBSTANCES

One pipette delivers:

| Unit dose | Pyriprole |
|-----------|-----------|
| 0.45 ml | 56.25 mg |

Excipients:

0.1 % Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution for external application to the skin

4. PACKAGE SIZE

3 pipettes

6 pipettes

30 pipettes

5. TARGET SPECIES

Dog (2-4.5 kg)

6. INDICATION(S)

Treatment and prevention of infestations with fleas and ticks.

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use for external application to the skin.

1. Remove one pipette from the package.
2. Hold the pipette in an upright position. Tap the narrow part of the pipette to ensure the contents are in the main body of the pipette. Snap-off the top of the pipette along the scored line.
3. Part the coat on the back of the animal between the shoulder blades until the skin is visible.
4. Place the tip of the pipette on the skin and squeeze the pipette gently several times at one or two spots to empty the contents onto the skin. Ensure the product is deposited on the skin.

Read the package leaflet before use.

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|--------------------------------|
| 8. WITHDRAWAL PERIOD(S) |
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| 9. SPECIAL WARNING(S), IF NECESSARY |
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Read the package leaflet before use.

Human safety information:

Avoid contact of the product with skin, eyes or mouth.

Avoid direct contact with the treated animal until the application site is dry.

Animal safety information:

Only indicated for use in dogs.

Do not use in cats or rabbits.

Do not give by mouth.

Avoid contact of the product with dogs's eyes.

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|------------------------|
| 10. EXPIRY DATE |
|------------------------|

EXP {month/year}

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| 11. SPECIAL STORAGE CONDITIONS |
|---------------------------------------|

Keep the pipettes in the original blister package until ready to use, in order to protect from light.

Do not store above 25°C

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| 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY |
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Disposal: read package leaflet.

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| 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE |
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For animal treatment only.

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| 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN" |
|--|

Keep out of the sight and reach of children.

| |
|---|
| 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER |
|---|

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

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| 16. MARKETING AUTHORISATION NUMBER(S) |
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EU/2/06/066/001 (3 pipettes)
EU/2/06/066/002 (6 pipettes)
EU/2/06/066/003 (30 pipettes)

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| 17. MANUFACTURER'S BATCH NUMBER |
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Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BLISTER 56.25 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic spot-on for dogs

Pyriprole

2. QUANTITY OF THE ACTIVE SUBSTANCE

56.25 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.45 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)**6. BATCH NUMBER**

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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| MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS |
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|-------------------------|
| PIPETTE 56.25 mg |
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|--|
| 1. NAME OF THE VETERINARY MEDICINAL PRODUCT |
|--|

Prac-tic 56.25 mg

Pyriprole

| |
|--|
| 2. NAME OF THE MARKETING AUTHORISATION HOLDER |
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Elanco

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|-----------------------|
| 3. EXPIRY DATE |
|-----------------------|

EXP {month/year}

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|------------------------|
| 4. BATCH NUMBER |
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Lot {number}

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| 5. THE WORDS “FOR ANIMAL TREATMENT ONLY” |
|---|

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**CARDBOARD CARTON 137.5 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic 137.5 mg spot-on solution for small dogs

2. STATEMENT OF ACTIVE SUBSTANCES

One pipette delivers:

| Unit dose | Pyriprole |
|-----------|-----------|
| 1.1 ml | 137.5 mg |

Excipients:

0.1 % Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution for external application to the skin

4. PACKAGE SIZE

3 pipettes

6 pipettes

30 pipettes

5. TARGET SPECIES

Dog (>4.5-11 kg)

6. INDICATION(S)

Treatment and prevention of infestations with fleas and ticks.

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use for external application to the skin.

1. Remove one pipette from the package.
2. Hold the pipette in an upright position. Tap the narrow part of the pipette to ensure the contents are in the main body of the pipette. Snap-off the top of the pipette along the scored line.
3. Part the coat on the back of the animal between the shoulder blades until the skin is visible.
4. Place the tip of the pipette on the skin and squeeze the pipette gently several times at one or two spots to empty the contents onto the skin. Ensure the product is deposited on the skin.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Human safety information:

Avoid contact of the product with skin, eyes or mouth.

Avoid direct contact with the treated animal until the application site is dry.

Animal safety information:

Only indicated for use in dogs.

Do not use in cats or rabbits.

Do not give by mouth.

Avoid contact of the product with dog's eyes.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the pipettes in the original blister package until ready to use, in order to protect from light.

Do not store above 25°C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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| 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE |
|---|

For animal treatment only.

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| 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN” |
|--|

Keep out of the sight and reach of children.

| |
|---|
| 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER |
|---|

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

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|--|
| 16. MARKETING AUTHORISATION NUMBER(S) |
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EU/2/06/066/004 (3 pipettes)
EU/2/06/066/005 (6 pipettes)
EU/2/06/066/006 (30 pipettes)

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| 17. MANUFACTURER’S BATCH NUMBER |
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Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BLISTER 137.5 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic spot-on for dogs

Pyriprole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

137.5 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1.10 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)**6. BATCH NUMBER**

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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| MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS |
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|-------------------------|
| PIPETTE 137.5 mg |
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|--|
| 1. NAME OF THE VETERINARY MEDICINAL PRODUCT |
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Prac-tic 137.5 mg

Pyriprole

| |
|--|
| 2. NAME OF THE MARKETING AUTHORISATION HOLDER |
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Elanco

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|-----------------------|
| 3. EXPIRY DATE |
|-----------------------|

EXP {month/year}

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|------------------------|
| 4. BATCH NUMBER |
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Lot {number}

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| 5. THE WORDS “FOR ANIMAL TREATMENT ONLY” |
|---|

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**CARDBOARD CARTON 275 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic 275 mg spot-on solution for medium dogs

2. STATEMENT OF ACTIVE SUBSTANCES

One pipette delivers:

| Unit dose | Pyriprole |
|-----------|-----------|
| 2.2 ml | 275 mg |

Excipients:

0.1 % Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution for external application to the skin

4. PACKAGE SIZE

3 pipettes
6 pipettes
30 pipettes

5. TARGET SPECIES

Dog (>11-22 kg)

6. INDICATION(S)

Treatment and prevention of infestations with fleas and ticks.

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use for external application to the skin

1. Remove one pipette from the package.
2. Hold the pipette in an upright position. Tap the narrow part of the pipette to ensure the contents are in the main body of the pipette. Snap-off the top of the pipette along the scored line.
3. Part the coat on the back of the animal between the shoulder blades until the skin is visible.
4. Place the tip of the pipette on the skin and squeeze the pipette gently several times at one or two spots to empty the contents onto the skin. Ensure the product is deposited on the skin.

Read the package leaflet before use.

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| 8. WITHDRAWAL PERIOD(S) |
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| 9. SPECIAL WARNING(S), IF NECESSARY |
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Read the package leaflet before use.

Human safety information:

Avoid contact of the product with skin, eyes or mouth.

Avoid direct contact with the treated animal until the application site is dry.

Animal safety information:

Only indicated for use in dogs.

Do not use in cats or rabbits.

Do not give by mouth.

Avoid contact of the product with dog's eyes.

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| 10. EXPIRY DATE |
|------------------------|

EXP {month/year}

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|---------------------------------------|
| 11. SPECIAL STORAGE CONDITIONS |
|---------------------------------------|

Keep the pipettes in the original blister package until ready to use, in order to protect from light.

Do not store above 25°C

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| 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY |
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Disposal: read package leaflet.

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| 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE |
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For animal treatment only.

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|--|
| 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN” |
|--|

Keep out of the sight and reach of children.

| |
|---|
| 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER |
|---|

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

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| 16. MARKETING AUTHORISATION NUMBER(S) |
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EU/2/06/066/007 (3 pipettes)
EU/2/06/066/008 (6 pipettes)
EU/2/06/066/009 (30 pipettes)

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| 17. MANUFACTURER'S BATCH NUMBER |
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Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BLISTER 275 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic spot-on for dogs

Pyriprole

2. QUANTITY OF THE ACTIVE SUBSTANCE

275 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2.20 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)**6. BATCH NUMBER**

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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| MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS |
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|-----------------------|
| PIPETTE 275 mg |
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|--|
| 1. NAME OF THE VETERINARY MEDICINAL PRODUCT |
|--|

Prac-tic 275 mg

Pyriprole

| |
|--|
| 2. NAME OF THE MARKETING AUTHORISATION HOLDER |
|--|

Elanco

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|-----------------------|
| 3. EXPIRY DATE |
|-----------------------|

EXP {month/year}

| |
|------------------------|
| 4. BATCH NUMBER |
|------------------------|

Lot {number}

| |
|---|
| 5. THE WORDS “FOR ANIMAL TREATMENT ONLY” |
|---|

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**CARDBOARD CARTON 625 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic 625 mg spot-on solution for large dogs

2. STATEMENT OF ACTIVE SUBSTANCES

One pipette delivers:

| Unit dose | Pyriprole |
|-----------|-----------|
| 5.0 ml | 625 mg |

Excipients:

0.1 % Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution for external application to the skin

4. PACKAGE SIZE

3 pipettes

6 pipettes

30 pipettes

5. TARGET SPECIES

Dog (>22-50 kg)

6. INDICATION(S)

Treatment and prevention of infestations with fleas and ticks.

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use for external application to the skin.

1. Remove one pipette from the package.
2. Hold the pipette in an upright position. Tap the narrow part of the pipette to ensure the contents are in the main body of the pipette. Snap-off the top of the pipette along the scored line.
3. Part the coat on the back of the animal between the shoulder blades until the skin is visible.
4. Place the tip of the pipette on the skin and squeeze the pipette gently several times at 2-3 spots down the back-line of large dogs to prevent runoff. Ensure the product is deposited on the skin.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Human safety information:

Avoid contact of the product with skin, eyes or mouth.

Avoid direct contact with the treated animal until the application site is dry.

Animal safety information:

Only indicated for use in dogs.

Do not use in cats or rabbits.

Do not give by mouth.

Avoid contact of the product with dog's eyes.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the pipettes in the original blister package until ready to use, in order to protect from light.

Do not store above 25°C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

| |
|---|
| 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER |
|---|

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

| |
|--|
| 16. MARKETING AUTHORISATION NUMBER(S) |
|--|

EU/2/06/066/010 (3 pipettes)
EU/2/06/066/011 (6 pipettes)
EU/2/06/066/012 (30 pipettes)

| |
|--|
| 17. MANUFACTURER'S BATCH NUMBER |
|--|

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BLISTER 625 mg****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prac-tic spot-on for dogs

Pyriprole

2. QUANTITY OF THE ACTIVE SUBSTANCE

625 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5.0 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)**6. BATCH NUMBER**

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

| |
|--|
| MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS |
|--|

| |
|-----------------------|
| PIPETTE 625 mg |
|-----------------------|

| |
|--|
| 1. NAME OF THE VETERINARY MEDICINAL PRODUCT |
|--|

Prac-tic 625 mg

Pyriprole

| |
|--|
| 2. NAME OF THE MARKETING AUTHORISATION HOLDER |
|--|

Elanco

| |
|-----------------------|
| 3. EXPIRY DATE |
|-----------------------|

EXP {month/year}

| |
|------------------------|
| 4. BATCH NUMBER |
|------------------------|

Lot {number}

| |
|---|
| 5. THE WORDS “FOR ANIMAL TREATMENT ONLY” |
|---|

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Prac-tic spot-on solution for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

Manufacturer for the batch release:

Elanco France S.A.S.
26, Rue de la Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prac-tic 56.25 mg spot-on solution for very small dogs
Prac-tic 137.5 mg spot-on solution for small dogs
Prac-tic 275 mg spot-on solution for medium dogs
Prac-tic 625 mg spot-on solution for large dogs

Pyriprole

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains 125 mg pyriprole as a colourless to yellow, clear solution for external application to the skin.

One pipette delivers:

| | Unit dose | Pyriprole |
|------------------------------|------------------|------------------|
| Prac-tic for very small dogs | 0.45 ml | 56.25 mg |
| Prac-tic for small dogs | 1.1 ml | 137.5 mg |
| Prac-tic for medium dogs | 2.2 ml | 275 mg |
| Prac-tic for large dogs | 5.0 ml | 625 mg |

The solution also contains 0.1 % Butylhydroxytoluene (E321)

4. INDICATION(S)

Treatment and prevention of flea infestation (*Ctenocephalides canis* and *C. felis*).

Treatment and prevention of tick infestation (*Ixodes ricinus*, *Ixodes scapularis*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*, *Amblyomma americanum*).

Treatment and prevention of flea infestation: Prac-tic is effective against new infestations with fleas for a minimum duration of 4 weeks.

Treatment and prevention of tick infestation: Prac-tic is effective against ticks for 4 weeks.

5. CONTRAINDICATIONS

Do not use in dogs less than 8 weeks of age or weighing less than 2 kg.

Do not use in case of known hypersensitivity to phenylpyrazole class compounds or to any of the excipients.

Do not use on sick animals or on animals recovering from disease.

The veterinary medicinal product is specifically developed for dogs.

Do not use in cats, as this could lead to overdosing.

Do not use in rabbits.

6. ADVERSE REACTIONS

On very rare occasions the following have been reported:

- application site and skin reactions :pruritus (itchy skin), hair change, dermatitis (inflammation of the skin), erythema (redness of skin), alopecia (loss of hair), fur discoloration and greasy appearance of hair.
- neurological reactions: ataxia (lack of coordination) and convulsions.
- systemic reactions: lethargy (drowsiness).
- digestive tract reactions: emesis (vomiting) and diarrhoea.

Those signs are usually transient and disappear within 24 hours of the application; if they take longer to disappear consult your veterinarian.

A brief period of hypersalivation (drooling) may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within minutes without treatment. Correct application will minimise licking of the application site.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dog

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For spot-on use for external application to the dog's skin.

Dosage Table

The recommended minimum dose is 12.5 mg pyriprole per kg bodyweight, equivalent to 0.1 ml spot-on solution per kg bodyweight.

| Weight range of dog (kg) | Pipette size to be used | One pipette of 12.5% (w/v) solution contains (ml) | Pyriprole (mg / kg bw) |
|---------------------------------|---|--|-------------------------------|
| 2 – 4.5 kg | Very small dog | 0.45 | 12.5 – 28.1 |
| 4.5 – 11 kg | Small dog | 1.1 | 12.5 – 30.6 |
| 11 – 22 kg | Medium dog | 2.2 | 12.5 – 25.0 |
| 22 – 50 kg | Large dog | 5.0 | 12.5 – 28.4 |
| Greater than 50 kg | Use the appropriate combination of pipettes to achieve the correct dose | | |

Within each weight range the entire contents of the correct size pipette should be deposited on the dog's skin.

Flea treatment and prevention

Pyriprole kills fleas within 24 hours after contact. One treatment prevents future flea infestation for 4 weeks.

Tick treatment and prevention

Pyriprole kills ticks within 48 hours after application. One treatment is effective against ticks for 4 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

For application on the skin only.

Remove one pipette from the package. Hold the pipette in an upright position. Tap the narrow part of the pipette to ensure the contents are in the main body of the pipette. Snap-off the top of the pipette along the scored line.

Part the coat on the back of the animal between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze it gently several times at one or two spots to empty the contents onto the skin. Ensure the product is deposited on the skin. Apply the 5 ml pipette to 2-3 spots down the backline of large dogs so as to prevent run-off.

The dogs should be accurately weighed before the treatment to ensure the correct pipette size is used.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the pipette after “EXP”.
Keep the pipettes in the original blister package until ready to use, in order to protect from light.
Do not store above 25°C.

12. SPECIAL WARNING(S)

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

People with known allergies to the phenylpyrazole class of compounds or any of the excipients should avoid contact with the product.

Avoid the contents coming into contact with your fingers. Wash your hands after use and wash off any product in contact with your skin with soap and water. If the product accidentally gets in your eyes, rinse them carefully with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the doctor

If you come into contact with the product, it may happen that your skin and mucosa become numb and irritated but these conditions usually disappear spontaneously.

If you or anybody else accidentally swallows this product, seek medical advice immediately and show this leaflet or the label to your doctor.

Do not smoke, eat or drink while handling the product.

As a precautionary measure, direct contact with the treated dogs should be avoided and children should not be allowed to play with treated dogs until the application site is dry. It is therefore recommended to treat dogs in the evening. Recently treated dogs should not be allowed to sleep in the same bed as their owners, especially children.

This veterinary medicinal product is for the treatment of ticks and adult fleas. All dogs in a household should be treated at the same time.

Special precautions for use in animals

Following treatment, ticks will drop off from the dog within 24 to 48 hours after coming into contact with the animal; however, single ticks might remain on the animal. For this reason, a transmission of infectious diseases by ticks cannot be completely excluded.

In cases of heavy infestation prior to treatment, the dog's surrounding should be vacuumed and treated with a suitable insecticide.

Apply only to the skin surface and on intact skin.

The product is for skin application on dogs only; do not put in your dog's mouth. Take care to avoid the veterinary medicinal product coming into contact with your dog's eyes.

Consult a veterinary surgeon if it is intended to use the product on dogs with other products or medication

Do not give the product by mouth as this can lead to an overdose, or any other route.

The safety of the product has not been established in breeding dogs, including pregnant or lactating dogs. If you suspect your dog may be pregnant or if your bitch is nursing puppies or if you want to treat a breeding dog, contact your veterinarian for advice before use.

Overdose (symptoms, emergency, procedures, antidotes):

Mild neurological signs such as slight incoordination and unsteadiness were observed in some animals treated once a month. Those signs disappeared within 3 hours following administration.

In one out of 8 dogs the following transient adverse effects were observed: tremors (shaking), ataxia (lack of coordination), panting and convulsions. These signs disappeared within 18 hours following administration.

Following an overdose on a single occasion the following adverse effects were seen: vomiting, anorexia (loss of appetite), reduced body weight, muscle tremors, seizures, unsteadiness, laboured breathing. All signs resolved within 48 hours, with the exception of the loss of appetite.

An overdose of the product may cause a sticky and tangled appearance of hair at the treatment spot for up to 24 hours.

In case of an overdose contact your veterinary surgeon

Apply the dose to an area where your dog cannot lick it off and do not allow your dog or other animals lick each other following treatment.

Dogs should not be bathed or shampooed from 48 hours before treatment. Immersion of your dog in water or shampooing within 24 hours after treatment may reduce the efficacy of the product. If you want to wash your dog, leave at least one day between treatment and shampooing.

When administering the product, try to avoid wetting the fur as this will lead to a sticky and tangled appearance. However, should this happen it will disappear within 24 hours.

The solvent in Prac-tic may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

Prac-tic should not enter water courses, as this may be dangerous for fish and other aquatic organisms.

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

These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>

15. OTHER INFORMATION

Adult fleas are killed before they lay eggs for a minimum of 4 weeks after treatment. Since Prac-tic completely eliminates egg production, it breaks the flea life cycle.

Cardboard carton containing 1, 2 or 10 blisters of 3 pipettes.

Not all pack sizes may be marketed.

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