

1.3.1	Fypryst 134 mg spot-on solution for dogs
SPC, Labeling and Package Leaflet	CZ

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

### **BOX**

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

Fypryst 134 mg spot-on solution for dogs  
Fipronil

#### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 pipette (1.34 ml) contains:

**Active substance:**

Fipronil 134 mg

**Excipients:**

Butylhydroxyanisol (E320) 0.27 mg

Butylhydroxytoluene (E321) 0.13 mg

#### **3. PHARMACEUTICAL FORM**

Spot-on solution

#### **4. PACKAGE SIZE**

1 unit-dose pipette of 4.02 ml  
3 unit-dose pipettes of 1.34 ml  
6 unit-dose pipettes of 4.02 ml  
10 unit-dose pipettes of 4.02 ml  
20 unit-dose pipettes of 4.02 ml

#### **5. TARGET SPECIES**

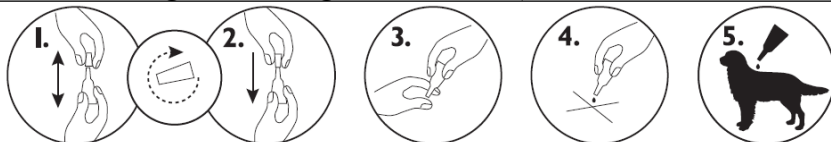
Dogs (10-20 kg)

#### **6. INDICATION(S)**

#### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Spot-on use.

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## 8. WITHDRAWAL PERIOD

## 9. SPECIAL WARNING(S), IF NECESSARY

Accidental contact with mucosa and skin is danger – see package leaflet before use.

## 10. EXPIRY DATE

EXP:

## 11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local requirements. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

## 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

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER’S BATCH NUMBER

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Lot:

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

**LABEL**

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

Fypryst 134 mg spot-on solution for dogs  
Fipronil

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Fipronil 134 mg

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

1 unit-dose pipette of 1.34 ml

**4. ROUTE(S) OF ADMINISTRATION**

Spot-on use.  
Dogs (10-20 kg)



**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

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

**PIPETTE**

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

Fypryst 134 mg spot-on solution for dogs  
Fipronil

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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

1.34 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

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