



23 January 2014

Revised: January 2014  
AN. 00515/2013

## **LABELLING**

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

**Box containing 1, 2, 3, 4 or 6 pipettes**

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

Dicrolin 402 mg Spot-on solution for very large dogs  
Fipronil

#### **2. STATEMENT OF ACTIVE SUBSTANCE**

One 4.02 ml pipette contains 402 mg of fipronil.

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

Spot-on solution.

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

1, 2, 3, 4 or 6 pipettes

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

Dogs.

#### **6. INDICATIONS**

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.

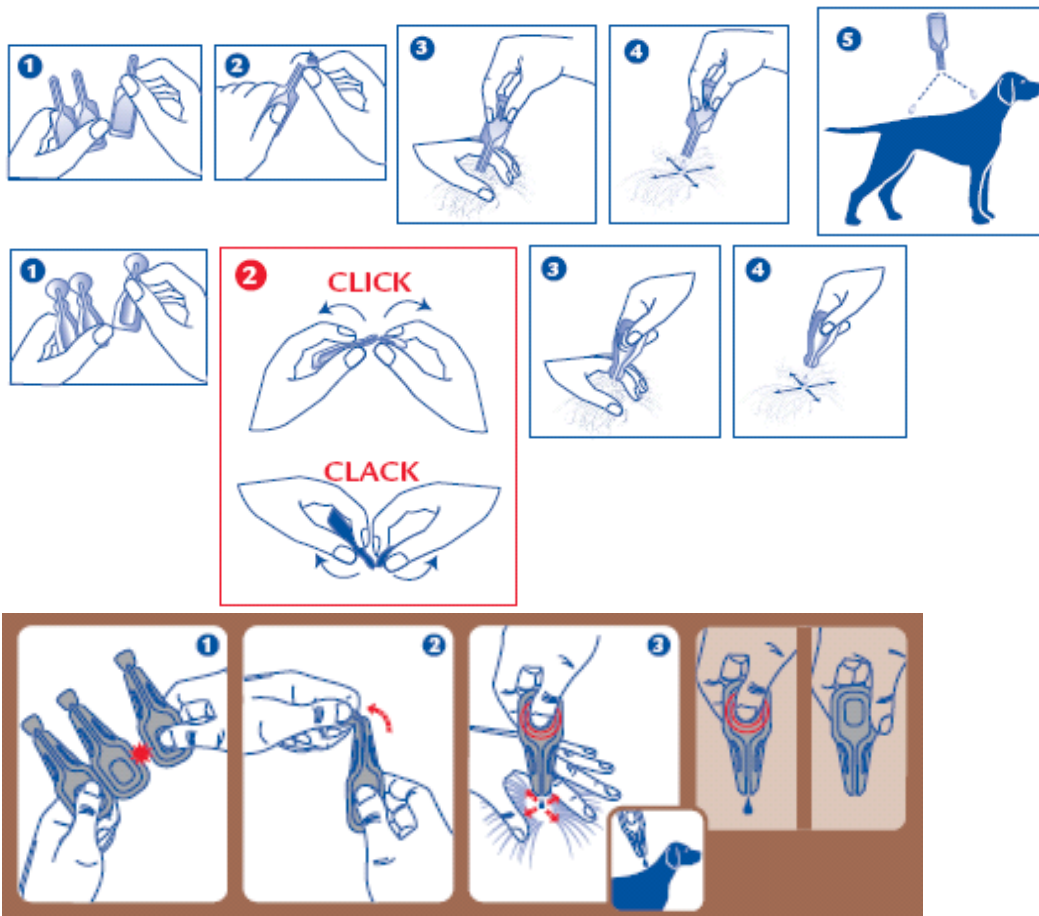
Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The product has a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

#### **7. METHOD AND ROUTE OF ADMINISTRATION**

External use only.

1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.  
For dogs over 60 kg use two pipettes of 2.68 ml.

Read the package leaflet before use.



(Note : the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)

## 8. WITHDRAWAL PERIOD

Not applicable.

## 9. SPECIAL WARNINGS

Do not remove from blister until required for use.

### User safety – Please read before every use

This product can cause mucous membrane and eye irritation. Therefore, do not get the product in your mouth or eyes.

In the case of accidental eye contact, immediately rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the packaging to the doctor.

Avoid contents coming into contact with the fingers. If this occurs, quickly wash hands with soap and water. Wash hands after use.

Do not smoke, drink or eat during application.

People with a known hypersensitivity (allergy) to fipronil or the other ingredients should avoid contact with this product.

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



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**10. EXPIRY DATE**

EXP :{month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store below 30°C. Store in a dry place. Store in the original package.

**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 REACH AND SIGHT OF CHILDREN”**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

ALFAMED  
13ème Rue – L.I.D.  
06517 CARROS CEDEX  
FRANCE

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

Vm 17902/4030  
AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

Batch : {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

**1 blister**

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



Dicrolin XL

**2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSE**

402 mg

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

(reference is made to the cat logo and drop in section 1)

**4. EXPIRY DATE**

EXP : {month/year}

**5. BATCH NUMBER**

Batch : {number}

**6. MARKETING AUTHORISATION HOLDER**

ALFAMED

**MINIMUM PARTICULARS TO APPEAR ON PIPETTES**

**1 pipette**

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



Dicrolin XL

**2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSE**

402 mg

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

(reference is made to the dog logo and drop in section 1)

**4. EXPIRY DATE**

EXP : {month/year}

**5. BATCH NUMBER**

Batch : {number}

**6. MARKETING AUTHORISATION HOLDER**

ALFAMED

**Dicrolin 100 mg/ml Spot-on solution  
for small, medium, large and very large 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 :

ALFAMED

13ème Rue – L.I.D.

06517 CARROS CEDEX

FRANCE

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

Dicrolin 100 mg/ml Spot-on solution for small, medium, large and very large dogs  
Fipronil

**3. CONTENTS**

**Active substance:**

Each ml contains 100 mg fipronil.

Each pipette of Dicrolin delivers the following amount :

	<b>Unit dose</b>	<b>Fipronil</b>
for small dogs (S)	0.67 ml	67 mg
for medium dogs (M)	1.34 ml	134 mg
for large dogs (L)	2.68 ml	268 mg
for very large dogs (XL)	4.02 ml	402 mg

**Other ingredients:**

	<b>Butylhydroxyanisole E320</b>	<b>Butylhydroxytoluene E321</b>
for small dogs (S)	0.134 mg/pipette	0.067 mg/pipette
for medium dogs (M)	0.268 mg/pipette	0.134 mg/pipette
for large dogs (L)	0.536 mg/pipette	0.268 mg/pipette
for very large dogs (XL)	0.804 mg/pipette	0.402 mg/pipette

**4. WHAT IS Dicrolin 100 mg/ml Spot-on solution for dogs USED FOR ?**

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The product has a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.



## **5. CONSIDERATIONS BEFORE YOU USE Dicrolin 100 mg/ml Spot-on solution for dogs**

Do not use on puppies less than 2 months old and /or weighing less than 2kg in the absence of available data.

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

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

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

## **6. POSSIBLE SIDE EFFECTS IN YOUR PET**

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

Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs.

## **8. HOW SHOULD I USE Dicrolin 100 mg/ml Spot-on solution for dogs?**

Route of administration and dosage:

External use only.

Administer by topical application to the skin according to the bodyweight as follows,

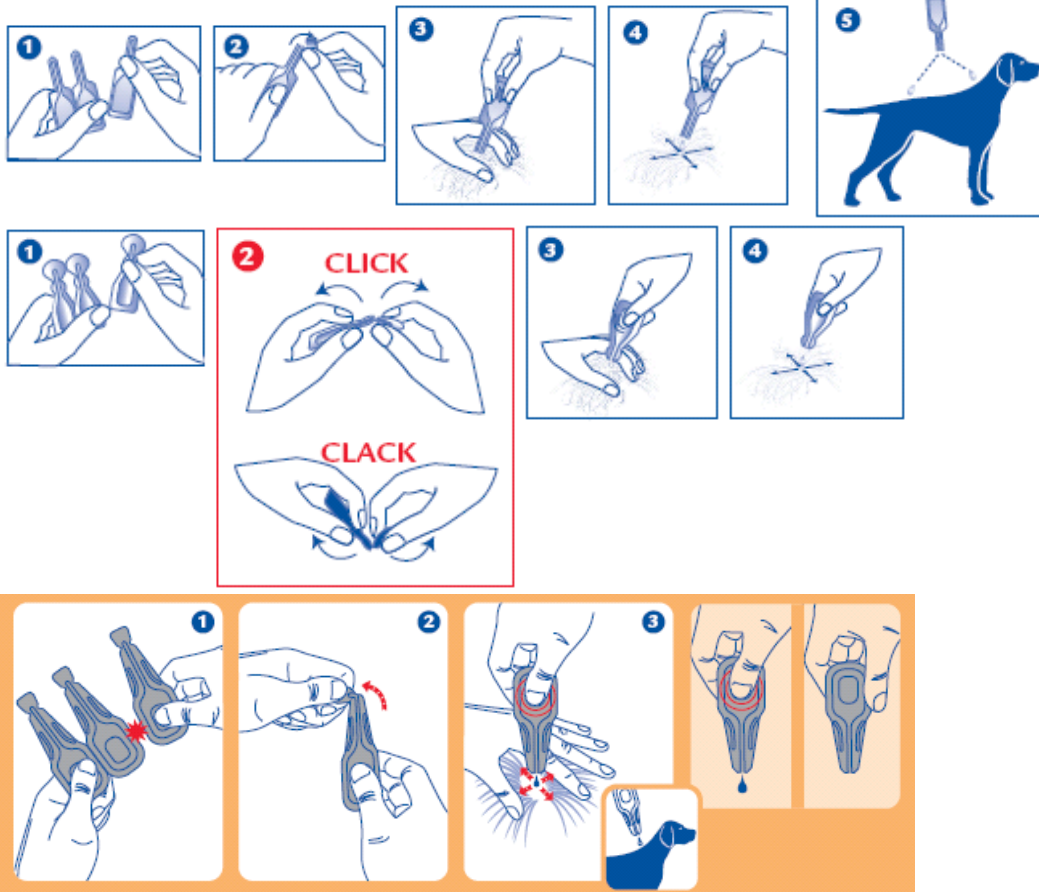
- \* 1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight
  - \* 1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight
  - \* 1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight
  - \* 1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight
- For dogs over 60 kg use two pipettes of 2.68 ml.

Method of administration:

*Thermoformed pipettes:*

Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.

Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the pet's back.

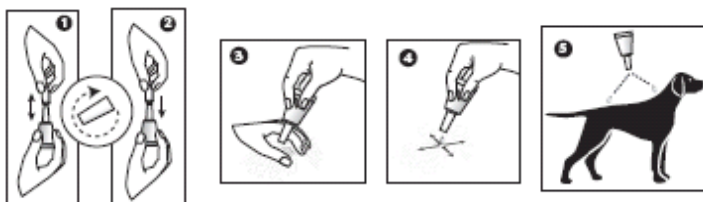


(Note : the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)

#### *Polypropylene pipettes:*

Remove the pipette from the blister packaging. Hold the pipette in an upright position, twist and pull the cap off. Turn the cap around and place the other end of the cap back on the pipette. Twist the cap to break the seal, then remove the cap from the pipette.

Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents. Repeat this procedure at one or two points along the pet's back.



It is important to make sure that the 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.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

(Note : There will be 2 insert leaflets, one for each type of pipette. However, for practical reasons both are stated on 1 insert leaflet.)

## **9. HOW OFTEN SHOULD I USE Dicrolin 100 mg/ml Spot-on solution for dogs?**

Treatment schedule:

In the absence of safety studies, the minimum treatment interval is 4 weeks. Please seek professional advice regarding the optimal treatment schedule for your pet.

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. STORAGE**

Keep out of the reach and sight of children.  
Store below 30°C. Store in a dry place. Store in the original package.  
Do not use after the expiry date stated on the carton and pipette after "EXP".

## **12. SPECIAL WARNINGS**

For Animal Treatment Only.  
Do not remove from blister until required for use.

### **Special warnings for use in animals**

Shampooing an hour prior to treatment does not affect the efficacy of the product against fleas.

Bathing/immersion in water within two days after application of the product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week.

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

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.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

### **Special precautions for use in animals**

Animals should be weighed accurately prior to treatment.



Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately rinse the eyes with clean water.

It is important to make sure that the 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

Do not apply the product on wounds or damaged skin.

**User safety – Please read before every use**

This product can cause mucous membrane and eye irritation. Therefore, do not get the product in your mouth or eyes.

In the case of accidental eye contact, immediately rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the label to the doctor.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, quickly wash hands with soap and water. Wash hands after use.

People with a known hypersensitivity to fipronil (allergy) or the other ingredients should avoid contact with the veterinary medicinal product.

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

**Other precautions**

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

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

**Use during pregnancy and lactation**

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

**13. DISPOSAL**

Dispose of empty packaging and any remaining product in the household refuse.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Pack sizes :

*Thermoformed pipettes* boxes of 1, 2, 3, 4 or 6 pipettes.

*Polypropylene pipettes*: blister cards or boxes of 1, 2, 3, 4 or 6 pipettes.

Not all pack sizes may be marketed.



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