

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**ECTOLINE DUO 268 mg/80 mg spot-on solution for large dogs**  
**FIPROVET DUO 268 mg/80 mg spot-on solution for large dogs (FR)**

**Box containing 1 individual pipette placed in 1 overblister**  
**Box containing 2 individual pipettes placed in 1 overblister**  
**Box containing 3 individual pipettes placed in 2 overblisters**  
**Box containing 4 individual pipettes placed in 2 overblisters**  
**Box containing 6 individual pipettes placed in 3 overblisters**




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

ECTOLINE DUO 268 mg/80 mg spot-on solution for dogs  
FIPROVET DUO 268 mg/80 mg spot-on solution for dogs (FR)  
Fipronil/Pyriproxyfen

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

Each pipette contains:

|   |          |              |
|---|----------|--------------|
| <br>[optional] | Fipronil | Pyriproxyfen |
| 2.68 ml   | 268 mg   | 80.4 mg      |

### 3. PHARMACEUTICAL FORM

Spot-on solution

### 4. PACKAGE SIZE



1  
2.68 ml



2  
2.68 ml



3  
2.68 ml



4  
2.68 ml



6  
2.68 ml

### 5. TARGET SPECIES

Dogs 20-40 kg

### 6. INDICATION(S)


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

Fleas, flea eggs & Ticks

[This information may be deleted according to the legal status/distribution category, depending on the decision that will be taken in each country].

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

Spot-on use.

| <br>[optional] | Dog      | Fipronil | Pyriproxyfen |
|---|----------|----------|--------------|
| 0.67 ml   | 2-10 kg  | 67 mg    | 20.1 mg      |
| 1.34 ml   | 10-20 kg | 134 mg   | 40.2 mg      |
| 2.68 ml   | 20-40 kg | 268 mg   | 80.6 mg      |
| 4.02 ml   | 40-60 kg | 402 mg   | 120.8 mg     |

For dogs over 60 kg the appropriate combination of pipettes should be used.

Read the package leaflet before use.



[optional]

**8. WITHDRAWAL PERIOD**

Withdrawal period: Not applicable.

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

Read the package leaflet before use.



[optional]

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C.

Store in a dry place.

Keep the blister pack in the outer carton in order to protect from light.



30°C

[optional]

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

Read the package leaflet before use.



[optional]

**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.



[optional]

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

Alfamed  
13<sup>e</sup>me rue - L.I.D  
06517 Carros Cedex  
France

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

Vm 017902/4090

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

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

**ECTOLINE DUO 268 mg/80 mg spot-on solution for large dogs**  
**FIPROVET DUO 268 mg/80 mg spot-on solution for large dogs (FR)**

**Overblister packed in 1 pipette blister or 2 pipette blisters divisible per pipette**

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

ECTOLINE DUO 268 mg/80 mg spot-on  
FIPROVET DUO 268 mg/80 mg spot-on (FR)  
Fipronil/Pyriproxyfen



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

Fipronil 268 mg  
Pyriproxyfen 80 mg

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

1 dose

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

Spot-on use.

**5. WITHDRAWAL PERIOD**

Not applicable.

**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 SMALL IMMEDIATE PACKAGING UNITS**

**ECTOLINE DUO 268 mg/80 mg spot-on solution for large dogs**  
**FIPROVET DUO 268 mg/80 mg spot-on solution for large dogs (FR)**

**Individual Pipette**

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

ECTOLINE DUO 268 mg/80 mg spot-on  
FIPROVET DUO 268 mg/80 mg spot-on (FR)  
Fipronil/Pyriproxyfen



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

|              |        |
|--------------|--------|
| Fipronil     | 268 mg |
| Pyriproxyfen | 80 mg  |

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

1 dose

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

Spot-on use.

**5. WITHDRAWAL PERIOD**

Not applicable.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

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

For animal treatment only.

**PACKAGE LEAFLET FOR:**

**Ectoline duo 67 mg/20 mg spot-on solution for small dogs**  
**Ectoline duo 134 mg/40 mg spot-on solution for medium dogs**  
**Ectoline duo 268 mg/80 mg spot-on solution for large dogs**  
**Ectoline duo 402 mg/120 mg spot-on solution for very large dogs**

**FIPROVET duo 67 mg/20 mg spot-on solution for small dogs**  
**FIPROVET duo 134 mg/40 mg spot-on solution for medium dogs**  
**FIPROVET duo 268 mg/80 mg spot-on solution for large dogs**  
**FIPROVET duo 402 mg/120 mg spot-on solution for very large dogs**  
**(FR)**

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

Marketing authorisation holder and manufacturer responsible for batch release:

Alfamed  
13<sup>e</sup>me rue - L.I.D  
06517 Carros Cedex  
France

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

Ectoline duo 67 mg/20 mg spot-on solution for small dogs  
Ectoline duo 134 mg/40 mg spot-on solution for medium dogs  
Ectoline duo 268 mg/80 mg spot-on solution for large dogs  
Ectoline duo 402 mg/120 mg spot-on solution for very large dogs

Fiprovvet duo 67 mg/20 mg spot-on solution for small dogs  
Fiprovvet duo 134 mg/40 mg spot-on solution for medium dogs  
Fiprovvet duo 268 mg/80 mg spot-on solution for large dogs  
Fiprovvet duo 402 mg/120 mg spot-on solution for very large dogs  
(FR)

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

| Each pipette contains:            | Active substances |              | Excipients |          |
|-----------------------------------|-------------------|--------------|------------|----------|
|                                   | Fipronil          | Pyriproxyfen | BHA        | BHT      |
| Pipette volume (single dose unit) |                   |              |            |          |
| 0.67 ml                           | 67 mg             | 20.1 mg      | 0.134 mg   | 0.067 mg |
| 1.34 ml                           | 134 mg            | 40.2 mg      | 0.268 mg   | 0.134 mg |
| 2.68 ml                           | 268 mg            | 80.4 mg      | 0.536 mg   | 0.268 mg |
| 4.02 ml                           | 402 mg            | 120.6 mg     | 0.804 mg   | 0.402 mg |



Clear, colourless to yellowish solution.

#### **4. INDICATIONS**

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

##### Against fleas:

Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). One treatment prevents further infestations for 7 weeks.

Prevention of the multiplication of fleas preventing flea eggs developing into adult fleas for 12 weeks after application.

##### Against ticks:

Treatment of infestations by ticks (*Ixodes ricinus*).

One treatment provides persistent acaricidal efficacy for 2 weeks against *Ixodes ricinus*, and for 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.

If ticks of some species (*Dermacentor reticulatus*, *Rhipicephalus sanguineus*) are present at the time of application, not all ticks may be killed within 48 hours.

#### **5. CONTRAINDICATIONS**

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

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

#### **6. ADVERSE REACTIONS**

Transient cosmetic effects such as wet appearance or slight scaling may occur at the application site.

According to the accumulated experience on these active ingredients within spot on pharmaceutical forms, transient cutaneous reactions at the application site (squamosis, local alopecia, pruritus, erythema, skin discolouration) and general pruritus or alopecia may be observed after use. In very rare instances, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), respiratory signs or vomiting might occur.

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

#### **7. TARGET SPECIES**

For dogs

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

Dosage:

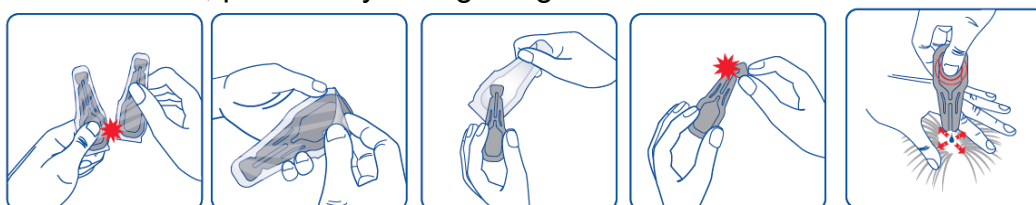
| Dog weight | Pipette volume (single dose unit) | Fipronil (mg) | Pyriproxyfen (mg) |
|------------|-----------------------------------|---------------|-------------------|
| 2-10 kg    | 0.67 ml                           | 67            | 20.1              |
| 10-20 kg   | 1.34 ml                           | 134           | 40.2              |
| 20-40 kg   | 2.68 ml                           | 268           | 80.4              |
| 40-60 kg   | 4.02 ml                           | 402           | 120.6             |

For dogs over 60 kg the appropriate combination of pipettes should be used.

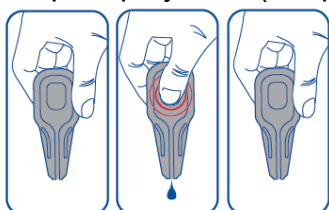
#### Method of administration:

Remove the pipette from the overblister. 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 on base of the neck before the shoulder blades until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently several times to empty the contents. If necessary the contents of the pipette can be administered at one or two additional point(s) along the pet's back to avoid run-off or more superficial application to the hair coat, particularly in large dogs.



Drop stop system (the product is released only by pressing the body of the pipette).



## **9. ADVICE ON CORRECT ADMINISTRATION**

One pipette provides a single treatment, with the possibility to repeat administrations on a monthly basis.

For optimal control of flea and tick infestations and flea multiplication, the treatment schedule can be based on the local epidemiological situation.

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in a dry place.

Keep the blister pack in the outer carton in order to protect from light.

## 12. SPECIAL WARNING(S)

### Special warnings for each target species:

Shampooing or immersion of the animal in water directly after treatment may reduce the duration of activity. The product remains effective against fleas for 5 weeks when the dog is shampooed at monthly intervals after treatment. If the dog requires shampooing, it is better to do so before treatment.

Water immersion repeated on two occasions post treatment did not affect adulticidal efficacy against fleas nor the efficacy related to the prevention of the development of flea eggs into adult fleas.

The influence of water immersion or shampooing of the dog on the efficacy of the product against ticks has not been evaluated.

At the beginning of the control measures, in the case of an infestation, the animal's basket, bedding and regular resting areas such as carpets and soft furnishings should be treated, with a suitable insecticide and vacuumed regularly.

To reduce environmental flea challenge, all animals living in the same household should also be treated with a suitable flea control product.

The product does not prevent ticks from attaching to animals. Transmission of infectious disease by ticks cannot be completely excluded if conditions are unfavourable. Immediate efficacy has been demonstrated against *Ixodes ricinus*, indicating that ticks of this species are likely to be killed within 48 hours of product application. If *Dermacentor reticulatus* or *Rhipicephalus sanguineus* ticks are present when the product is applied, these ticks may not be killed within the first 48 hours.

Once dead, ticks will often drop off the animal. Any remaining ticks should be carefully removed, ensuring that their mouth parts are not left within the skin.

### Special precautions for use in animals:

For external use only.

Animals should be weighed accurately prior to treatment.

In absence of safety data, the product should not be used in puppies less than 10 weeks old and/or weighing less than 2 kg.

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not apply the product on wounds or damaged skin.

In the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks.

The use of the product has not been studied in sick and debilitated dogs.

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

The product may cause neurotoxicity.  
The product may be harmful if swallowed.  
Avoid contact with skin and mouth.  
Avoid ingestion including hand-to-mouth contact.  
Do not smoke, drink or eat during application.  
Wash hands after use.

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 should not be allowed to sleep with owners, especially children.

Keep the pipettes in the original packaging until ready for use and dispose of used pipettes immediately.

In the case of accidental skin contact, flush with water.

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

For animal treatment only.

#### Other precautions

Fipronil and pyriproxyfen may adversely affect aquatic organisms. Dogs should be prevented from accessing streams and rivers for 48-hours following treatment.

The product may have adverse effects on painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

#### Pregnancy and lactation:

Laboratory studies using fipronil and pyriproxyfen 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 according to the benefit/risk assessment by the responsible veterinarian.

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

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

No serious adverse effects were observed in a safety study in 10-week old puppies treated with up to 5 times the maximum recommended dose 3 times at intervals of 4 weeks and with the maximum recommended dose 6 times at intervals of 4 weeks.

The risk of experiencing adverse reactions (see section 6) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

#### Incompatibilities:

None known.

### **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 product should be disposed of in accordance with local requirements.

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container as this may be dangerous for fish and other aquatic organisms.

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

June 2017

#### 15. OTHER INFORMATION

**Pyriproxyfen** is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues. It prevents, by contact, the emergence of adult insects by blocking the development of eggs (ovicidal effect), larvae and pupae (larvicidal effect), which are subsequently eliminated.

**Combination of fipronil and pyriproxyfen** provides an insecticidal and acaricidal activity against fleas (*Ctenocephalides felis*), ticks (*Rhipicephalus sanguineus*, *Dermacentor reticulatus*, *Ixodes ricinus*) in addition to preventing flea eggs developing into adult fleas.

Boxes of 1, 2, 3, 4 and 6 pipettes.  
Not all pack sizes may be marketed.



Approved 15 June 2017