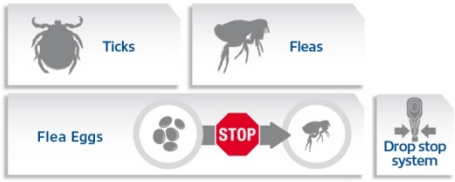
PARTICULARS TO APPEAR ON THE OUTER PACKAGE

ECTOLINE DUO 50 mg/60 mg spot-on solution for cats

Box containing 1 individual pipette placed in overblister
Box containing 4 individual pipettes placed in 1 overblister



1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECTOLINE DUO 50 mg/60 mg spot-on solution for cats
Fipronil/Pyriproxyfen

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml pipette contains: Fipronil 50 mg – Pyriproxyfen 60 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1
0.5 ml

4
0.5 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

To be used against infestations with fleas alone or in association with ticks.
Fleas, flea eggs & Ticks

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.

[optional]	Cat	Fipronil	Pyriproxyfen
1x 0.5 ml	1-6kg	50 mg	60 mg
2 x 0.5 ml	>6-12 kg	100 mg	120 mg

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

Disposal: read package leaflet.

[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
13ème rue - L.I.D.
06517 Carros Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17902/5038

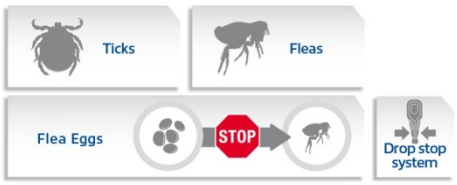
17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

ECTOLINE DUO 50 mg/60 mg spot-on solution for cats

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



1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECTOLINE DUO 50 mg/60 mg spot-on
Fipronil/Pyriproxyfen

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil	50 mg
Pyriproxyfen	60 mg

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

Pipette volume 0.5 ml

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 50 mg/60 mg spot-on solution for cats

Individual Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECTOLINE DUO 50 mg/60 mg spot-on
Fipronil/Pyriproxyfen

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 50 mg
Pyriproxyfen 60 mg

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

Pipette volume 0.5 ml

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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Ectoline duo 50 mg/60 mg spot-on solution for cats
Ectoline duo 100 mg/120 mg spot-on solution for very large cats

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

Manufacturer responsible for batch release:
ALFAMED
13ème Rue – L.I.D.
06517 CARROS CEDEX
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectoline duo 50 mg/60 mg spot-on solution for cats
Ectoline duo 100 mg/120 mg spot-on solution for very large cats

Fipronil/Pyripoxyfen

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

Each pipette contains:	Active substances		Excipients	
Pipette volume (single dose unit)	Fipronil	Pyriproxyfen	BHA*	BHT**
0.5 ml	50 mg	60 mg	0.1 mg	0.05 mg
1 ml	100 mg	120 mg	0.2 mg	0.10 mg

*: Butylhydroxyanisole E320, **: Butylhydroxytoluene E321

Clear, colourless to yellowish solution.

4. INDICATION(S)

In cats, 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 5 weeks.

Prevention of the multiplication of fleas by preventing flea eggs developing into adult fleas for 12 weeks after application.
The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

Against ticks:
Treatment of infestations by ticks (*Ixodes ricinus* and *Rhipicephalus turanicus*). One treatment provides persistent acaricidal efficacy for one week.
If ticks 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 can occur very rarely 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 as squamosis (scaling of the skin), local alopecia (hair loss), pruritus (itchiness), erythema (redness of the skin), skin discolouration and general pruritus or alopecia may very rarely be observed after use. Hypersalivation, reversible neurologic symptoms as hyperesthesia (increased sensitivity to stimuli), depression and nervous symptoms may very rarely be observed.

Respiratory signs or vomiting might occur in very rare cases.

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

For cats

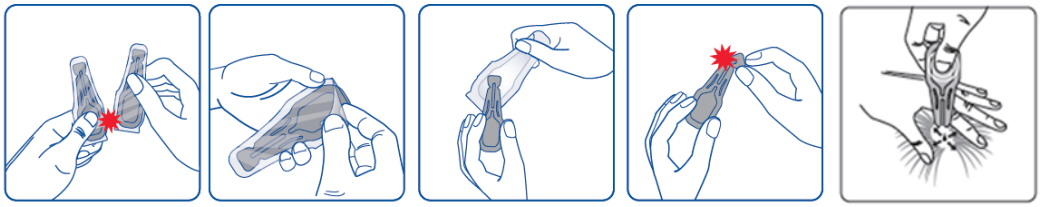
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Spot-on use.

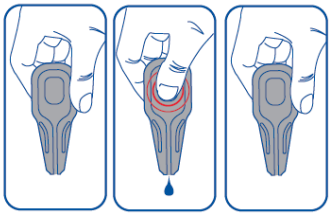
Dosage:
The minimum recommended dose is 8.3 mg fipronil/kg b.w. and 10 mg pyriproxyfen/kg b.w..
For a cat weighing at least 1 kg and up to 6 kg apply one pipette of 0.5 ml per cat.
For a cat weighing over 6 kg a recommended dose of 1 ml should be applied, which can be achieved by applying one pipette of 1 ml (or alternatively two pipettes of 0.5 ml).

Cat weight	Pipette volume		Fipronil (mg)	Pyriproxyfen (mg)
1-6 kg	0.5 ml		50	60
>6-12 kg	1 ml		100	120

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 coat on the back of neck area until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents evenly at one or two spots. Ensure the solution is applied to healthy skin only and avoid superficial application to the cat's hair or run off, especially in large cats (over 6 kg).



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



9. ADVICE ON CORRECT ADMINISTRATION

Consult your veterinary surgeon if the product fails to control the flea and tick infestation. However, in the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks (see section Overdose).

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:

Wetting of the haircoat with water 2 hours before product application and twice during the claimed period of efficacy against fleas (at two week intervals against adult fleas or four week intervals against developing flea stages) was investigated during two laboratory studies. Wetting of the haircoat with water as described did not adversely affect product effectiveness.
The impact of shampooing on product effectiveness has not been investigated. If a cat requires shampooing it is recommended that this is done before applying the veterinary medicinal product.

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. If the animal has been treated prior to exposure to the ticks, the ticks will be killed within 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. 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.
Do not administer orally.
Animals should be weighed accurately prior to treatment.
The safety of the product has not been established in cats younger than 10 weeks of age or in cats weighing less than 1.0 kg.
Avoid contact with the animal’s eyes. In the case of accidental eye contact, flush the eyes with water.

Care should be taken to apply the product correctly as described under section 'Method of administration'. Do not apply the product on wounds or damaged skin. It is important to make sure that the veterinary medicinal product is applied directly

onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

The use of the product has not been studied in sick or debilitated cats.

Consult your veterinary surgeon before using the product if your cat is unwell or currently receiving any other veterinary treatment.

Inform your veterinary surgeon that you are using this product if s/he provides your cat with any other medication.

Seek veterinary advice if the product is accidentally ingested or comes into contact with your animal's eyes.

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

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 ingestion including hand-to-mouth contact.
Do not smoke, drink or eat during application.
In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This product can cause eye and mucous membrane irritation.
Avoid contact with skin, eye and mouth, including hand to eye contact.
In the case of accidental skin or eye contact, immediately and thoroughly flush with water. If skin or eye irritation persists, seek medical advice and show the package leaflet or the label to the physician.
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.

For animal treatment only.

Other precautions
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. The safety of the product has not been established in pregnant and lactating queens. Consult your veterinary surgeon before using the product in pregnant or lactating queens.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea or tick products which are applied directly on to the animal.

Overdose (symptoms, emergency procedures, antidotes):
No serious adverse effects were observed in a target animal safety study in 10-week old kittens 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 Adverse Reactions) 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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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 turanicus*, *Ixodes ricinus*) in addition to preventing flea eggs developing into adult fleas.
Such combination provides an integrated flea control which can be used against infestations with fleas alone or in association with ticks.

Boxes of 1 and 4 pipettes.
Not all pack sizes may be marketed.

Ectoline duo 50 mg/60 mg spot-on solution for cats - Vm 17902/5038
Ectoline duo 100 mg/120 mg spot-on solution for very large cats - Vm 17902/5034

Gavin Hall

Approved 13 June 2025