



FIPROLINE DUO[®]



Product information

CONTENTS

1 	Name of veterinary medicinal product	3
2 	Qualitative and quantitative composition	3
3 	Pharmaceutical form	3
4 	Indications	3
5 	Administration and posology	3
6 	Interval between applications	4
7 	Special warnings	4
8 	Adverse reactions	5
9 	Precautions	5
10 	Withdrawal periods	6
11 	Storage conditions	6
12 	Presentations	6
13 	Shelf life	6

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproline Duo Pour-on and Spot-on.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml contains:

Fipronil 3 g

Excipients q.s.p. 100,00 mL

3. PHARMACEUTICAL FORM

Solution for topical use (Pour-on and Spot-on).

4. INDICATIONS

Fiproline Duo is indicated for cattle for the treatment against horn flies (*Haematobia irritans*) and stable flies (*Stomoxys calcitrans*), warble (*Dermatobia hominis* larvae) and ticks (*Rhipicephalus (Boophilus) microplus*). Also indicated for the prevention and treatment of myiasis resulting from infestation by *Cochliomyia hominivorax* larvae.

5. ADMINISTRATION AND POSOLOGY

Administer Fiproline Duo in cattle, through topical administration, for the treatment and control of infestations caused by:

- Horn flies (*Haematobia irritans*) and ticks (*Rhipicephalus (Boophilus) microplus*): one single dose, pour-on (along the back of the animal), 1 mg of fipronil/kg of live bodyweight, which corresponds to 1 mL of Fiproline Duo/30 kg of live bodyweight.
- Stable fly (*Stomoxys calcitrans*), warble (*Dermatobia hominis*) and myiasis resulting from infestation by *Cochliomyia hominivorax* larvae: single dose, spot-on, (single point, preferably in the dorso-cervical region - withers), 2 mg of fipronil/kg of live bodyweight, which corresponds to 2 mL of Fiproline Duo/30 kg of live bodyweight.

The table below shows the dosing scheme of the veterinary product:

Live bodyweight (kg)	Pour-on 1 mg of fipronil/kg BW	Spot-on 2 mg of fipronil/kg BW
	Volume to administer (mL)	Volume to administer (mL)
<30	1	2
60	2	4
90	3	6
120	4	8
150	5	10
210	7	14
270	9	18
330	11	22
390	13	26
450	15	30
510	17	34

As it is easy to apply, it avoids stress and facilitates handling. It contains a red dye in its formulation, which helps in visualizing the treated animals.

6. INTERVAL BETWEEN APPLICATIONS

Studies carried out with the veterinary product have shown that the efficacy against flies lasts for 35 days, the efficacy against warble for 28 days and the anti-tick efficacy for 23 days after treatment.

7. SPECIAL WARNINGS

- The veterinary product is not recommended for cows producing milk for human consumption;
- Do not use in animals sensitive to fipronil;
- The safety of Fiproline Duo has not been evaluated in under breeding activities, pregnant or lactating animals;
- The veterinary product is not recommended for cows producing milk for human consumption;
- The effectiveness of the veterinary product has not been tested on wet animals or in animals that are bathed immediately after application;
- The veterinary product can be used in cattle from 12 months of age.

8. ADVERSE REACTIONS

- Individual hypersensitivity reactions may occur. In these cases, symptomatic treatment is indicated. Do not treat the animal again with the veterinary product;
- In case of adverse reactions, please report immediately to the veterinarian.

9. PRECAUTIONS

- Respect the dosages and recommendations for use of the veterinary product;
- Use only on cattle;
- Do not apply on rainy days;
- Do not smoke or eat while handling the veterinary product;
- Always wash your hands after handling any veterinary product;
- Apply the veterinary product as indicated in the leaflet;
- Use with caution in weakened, elderly or sick animals;
- When handling the veterinary product, use appropriate personal protective equipment (gloves, mask, overalls);
- Toxic to fish and aquatic invertebrates;
- Do not store or apply near food, drinks, other medicines, personal hygiene or household products;
- Keep this, or any other veterinary medicine, out of the reach of children and domestic animals;
- Do not reuse empty packaging and dispose them in accordance with current legislation, to avoid environment contamination;
- Avoid contact with skin, eyes, mucous membranes and mouth and the inhalation of the veterinary product;
- In case of contact with skin and eyes, it is recommended to wash with plenty of running water. If the irritation persists, consult a doctor taking the veterinary product leaflet. In case of accidental ingestion, you should seek medical advice taking the veterinary product leaflet with you. It is possible for vomiting to occur spontaneously and should not be avoided; in this case, place the patient in lateral decubitus to prevent them from aspirating residues.

Note to the doctor:

In case of ingestion, the intoxication can be reduced by causing vomiting within half an hour of exposure. Treatment of poisoning must be symptomatic and, in severe cases, until the patient stabilizes. Considering the mechanism of action of fipronil, it is advisable to avoid medications that stimulate the GABA effect, such as barbiturates, benzodiazepines and valproic acid. There is no known antidote.

10. WITHDRAWAL PERIODS

Cattle:

Meat and offal: 67 days

Milk: this veterinary product must not be applied to cattle producing milk for human consumption.

The use of the veterinary product in conditions other than those indicated in the package leaflet may cause the presence of residues of the veterinary product above the approved limits, making the food of animal origin unfit for consumption.

11. WITHDRAWAL PERIODS

Store in a dry place, away from sunlight and at a temperature between 15° and 30°C.

Keep out of reach of children and domestic animals.

12. PRESENTATIONS

Plastic vials containing 250 mL, 1 L or 5 L of veterinary product. Not all pack sizes may be marketed.

13. SHELF LIFE

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.

Shelf-life after first opening the immediate packaging: 6 months.

Sale under prescription and administration under the guidance of the veterinarian.