

For the use only of a Registered Veterinary Practitioner or a Hospital or a Laboratory or a Farm

Milbemycin Oxime & Lufenuron Tablet

Milberon™ Yum-Tab!

Prevents heartworm disease and flea populations in dogs and puppies.



COMPOSITION:

Each uncoated tablet contains:
Milbemycin Oxime.....2.3 mg
Lufenuron46 mg
Excipients.....q.s.

COMPOSITION:

Each uncoated tablet contains:
Milbemycin Oxime.....5.75 mg
Lufenuron115 mg
Excipients.....q.s.

COMPOSITION:

Each uncoated tablet contains:
Milbemycin Oxime.....11.5 mg
Lufenuron230 mg
Excipients.....q.s.

COMPOSITION:

Each uncoated tablet contains:
Milbemycin Oxime.....23 mg
Lufenuron460 mg
Excipients.....q.s.

DESCRIPTION:

Milbemycin oxime consists of the oxime derivatives of 5-didehydromilbemycins in the ratio of approximately 80% A (C₁₈H₁₉NO, MW 555.71) and 20% B (C₁₈H₁₉NO, MW 541.68). Milbemycin oxime is classified as a macrocyclic anthelmintic. Lufenuron is a benzoylphenylurea derivative with the following chemical composition: N-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy)-phenylaminocarbonyl]-2,6-difluorobenzamide (C₁₈H₁₁Cl₂F₇NO, MW 511.15). Benzoylphenylurea compounds, including lufenuron, are classified as insect development inhibitors (IDIs).

INDICATIONS:

Milberon Tablets are indicated for use in dogs and puppies, four weeks of age and older and two pounds body weight or greater. It is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* for the prevention and control of flea populations, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis* and *Toxascaris leonina* (roundworm) and *Trichuris vulpis* (whipworm) infections. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of an adulticide product may be necessary for adequate control of adult fleas.

Without concurrent use of an adulticide, adequate flea control may not be achieved in dogs that have repeated exposure to flea infested animals or environments.

DOSAGE AND ADMINISTRATION: Milberon Tablets are given orally, once a month, at the recommended minimum dosage of 0.23 mg/lb (0.5 mg/kg) milbemycin oxime and 4.55 mg/lb (10mg/kg) lufenuron.

For dogs over 100 lb / 45 Kgs use the appropriate combination Or as directed by the Veterinarian.

Administration: To ensure adequate absorption, always administer Milberon Tablets to dogs immediately after or in conjunction with a normal meal.

Recommended Dosage Schedule

Dog Body Weight		Tablet per month	Milbemycin Oxime Content	Lufenuron Content
Up to 4.5 Kg	Up to 10 lbs	1	2.3 mg	46 mg
5 to 11 Kg	11 to 25 lbs	1	5.75 mg	115 mg
12 to 22 Kg	26 to 50 lbs	1	11.5 mg	230 mg
23 to 45 Kg	51 to 100 lbs	1	23 mg	460 mg

TARGET SPECIES: Dogs

PHARMACODYNAMIC PROPERTIES: Pharmacotherapeutic group: Milbemycin oxime Anthelmintic, Lufenuron Insect, Growth Regulator ATC Vet Code: QP54AB51

PHARMACODYNAMICS:

Milbemycin belongs to the group of macrocyclic lactones, isolated from the fermentation of *Streptomyces hygroscopicus* var. *aureolacrimosus*. Out of the selected analogues, the one currently used for medicinal purposes is 80). As one of the active principles in 20 : Milbemycin A3/A4 oxime (ratio Milberon , it is effective against larval stages (L3, L4, and the microfilariae) of *Dirofilaria immitis*, and anthelmintic activity against the following nematodes: *Toxocara canis*, *Trichuris vulpis*, *Ancylostoma caninum*. The activity of milbemycin is correlated with its action on invertebrate neurotransmission: it potentiates GABA (gamma-amino-butyric acid), an inhibitor of neuromuscular transmission, leading to paralysis. Lufenuron belongs to the chemical group of benzoylureas, and is considered an IGR (Insect Growth Regulator) or IDI (Insect Development Inhibitor). It inhibits the development of fleas by interfering with the normal synthesis, polymerisation and deposition of the chitin, the principal component of the arthropod exoskeleton. The adult flea absorbs lufenuron via its blood meal. At therapeutic levels, lufenuron has no effect upon adult fleas, but passes transovarially to act upon certain stages of the development of the insect (egg and larva), thus interrupting the insect life cycle. Also, adult flea faeces containing lufenuron exert a larvicidal effect when ingested by the larvae directly.

PHARMACOKINETICS:

Milbemycin oxime is characterised by gastro-enteric absorption. It reaches peak plasma concentrations of about 200 - 300 ng/mL within about 2 to 5 hours after oral administration at recommended dose. Thereafter, milbemycin oxime concentrations decrease in plasma with a half life of about 1 to 3 days. Following oral administration, lufenuron is distributed via the blood to the adipose tissue, from which, metabolically unmodified, it is constantly released above the minimum effective concentration for at least one month.

WARNING & PRECAUTION:

Ideally, tablets are administered on the same day each month. If an interval is greater than 6 weeks, treatment should be resumed immediately and be continued at monthly intervals and, in case of heartworm prevention, a veterinarian should be consulted. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Do not use in puppies less than four weeks of age and less than two pounds of body weight. Prior to administration, dogs should be tested for existing heartworm infections. Infected dogs should be treated to remove adult heartworms and microfilariae prior to initiating treatment. Mild, transient hypersensitivity reactions manifested as labored respiration, vomiting, salivation and lethargy have been noted in some treated dogs carrying a high number of circulating microfilariae.

CONTRAINDICATIONS: Hypersensitivity to any of the Ingredients.

PREGNANCY AND LACTATION: Can be used during pregnancy & lactation.

DRUG INTERACTIONS:

During treatment with MILBERON, no other antiparasitic macrocyclic lactones should be administered.

ADVERSE EFFECTS: The following adverse reactions have been reported in dogs after giving milbemycin oxime or lufenuron: vomiting, depression/lethargy, pruritus, urticaria, diarrhea, anorexia, skin congestion, ataxia, convulsions, hypersalivation, and weakness.

OVERDOSAGE: At 10x recommended dose rate (i.e. 5 mg milbemycin oxime, 100 mg lufenuron per Kg) and higher dose rates clinical signs such as transient ataxia, trembling, depression & salivation may be observed. There is no specific antidote.

WITHDRAWAL PERIOD: Not Applicable

STORAGE: Store below 30°C in a dry place.

PRESENTATION: 1 Blister containing 6 Tablets is packed in a Carton along with the Pack Insert.

FOR VETERINARY USE.
NOT FOR HUMAN USE.
FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH OF CHILDREN & PETS, AWAY FROM FOOD.
Carefully read the accompanying instructions before use.

Manufactured and Marketed By:

Veko Care Pvt. Ltd.

Customer care : care@vekocare.com

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