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

nulura

न्यूलूरा

(Fluralaner Chewable Tablets 112.5 mg / 250 mg / 500 mg / 1000 mg / 1400 mg)

WARNING: To be sold by the retail on the prescription of a Veterinarian only.

Statement of active Substance:

Composition :
Fluralaner Chewable Tablets 112.5 mg for very small dogs
Each chewable tablet contains:
Fluralaner 112.5 mg
Excipients Q.S.

Fluralaner Chewable Tablets 250 mg for small dogs
Each chewable tablet contains:
Fluralaner 250 mg
Excipients Q.S.

Fluralaner Chewable Tablets 500 mg for medium dogs
Each chewable tablet contains:
Fluralaner 500 mg
Excipients Q.S.

Fluralaner Chewable Tablets 1000 mg for large dogs
Each chewable tablet contains:
Fluralaner 1000 mg
Excipients Q.S.

Fluralaner Chewable Tablets 1400 mg for very large dogs
Each chewable tablet contains:
Fluralaner 1400 mg
Excipients Q.S.

The table below shows the five tablet strengths and the dog body weight ranges.

nulura chewable tablets	Fluralaner (mg)
For very small dogs (2 – 4.5 kg)	112.5
For small dogs (> 4.5 – 10 kg)	250
For medium-sized dogs (>10 – 20 kg)	500
For large dogs (> 20 – 40 kg)	1000
For very large dogs (> 40 – 56 kg)	1400

Pharmaceutical form:
Chewable tablet.

Ectoparasiticides for systemic use.

Indication (s):
For the treatment of tick and flea infestations on dogs for 3 months. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile Ixodes ricinus, Ixodes hexagonus, Ixodes scapularis, Ixodes holocyclus, Dermacentor reticulatus, Dermacentor variabilis and Rhipicephalus sanguineus) and flea (Ctenocephalides felis and Ctenocephalides canis) killing activity for 3 months. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. The onset of effect is within 8 hours of attachment for fleas (C. felis) and 12 hours of attachment for ticks (I. ricinus). The product provides protection against transmission of Babesia canis by Dermacentor reticulatus ticks by killing the ticks before disease transmission occurs. This has been shown over a 3 months period after treatment.
The product effectively controls environmental flea populations in areas to which treated dogs have access. Can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).
For the treatment of Demodicosis caused by Demodex spp. mites. In a controlled trial, treatment with fluralaner resulted in the complete removal of Demodex spp. mites from treated dogs.
For the treatment of Sarcoptic mange and Otodectes spp. mite infestations.
Contraindications:
Do not use in case of hypersensitivity to the active substances or to any of the excipients

Adverse reactions:
Singular cases (1.6%) of mild and transient gastrointestinal symptoms such as diarrhea/vomiting/in appetence/drooling related to the root of administration of the product were observed in clinical studies.
Lethargy, muscle tremor, ataxia and convulsion have been reported very rarely in spontaneous reports. Most reported adverse reactions were self-limiting and of short duration.

Target Species: Dogs

Amount to be administered and administration route:
nulura chewable tablets should be administered in accordance with the following table:
(corresponding to a dose of 25 -56 mg fluralaner/kg body weight within one weight band)

Body weight (kg)/dog	Number & strength of tablet to be administered				
	nulura 112.5 mg	nulura 250 mg	nulura 500 mg	nulura 1000 mg	nulura 1400 mg
2-4.5	1				
>4.5-10		1			
>10-20			1		
>20-40				1	
>40-56					1

The chewable tablet should not be broken or divided. For dogs above 56 kg body weight, use combination of two tablets that most closely matches the body weight.

Method of administration:
Administer the nulura chewable tablet at or around the time of feeding. If the tablet is not taken up voluntarily by the dog it can also be given with food or directly into the mouth. The dog should be observed during administration to confirm that the tablet is swallowed.

Treatment schedule:
For optimal control of flea infestation, nulura should be administered at the interval of 3 months.
For optimal control of tick infestation, the timing of re-treatment depends on the tick species. Please refer indications. nulura may be administrated year around.
For the treatment of mite infestations, a single dose of the product should be applied. The need for and frequency of re-treatment should be in accordance with the advice of the prescribing veterinarian.

Overdose:
No adverse reactions were observed following oral administration to puppies aged 8-9 weeks and weighing 2.0-3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (56 mg, 168 mg and 280 mg fluralaner/kg body weight) on three occasions at shorter intervals than recommended (8-week intervals).
There were no findings on reproductive performance and no findings of concern on offspring viability when fluralaner was administered orally to Beagle dogs at overdoses of up to 3 times the maximum recommended dose (up to 168 mg/kg of fluralaner).
The veterinary medicinal product was well tolerated in Collies with a deficient Multidrug-Resistance-Protein 1 (MDR1 -/-) following single oral administration at 3 times the recommended dose (168 mg/kg BW). No treatment-related clinical signs were observed.

Special warning(s):
The risk of transmission of parasite borne diseases is substantially reduced due to the rapid onset of acaricidal and insecticidal action. Parasites need to start feeding on the host to become exposed to fluralaner; therefore the risk of the transmission of parasite borne diseases cannot be excluded if conditions are unfavourable.

Special Precautions for use:
Special precautions for use in animals:
In the absence of available data, the product should not be used on puppies less than 8 weeks old and /or dogs weighing less than 2 kg.
The product should not be administered at intervals shorter than 8 weeks as the safety for shorter intervals has not been tested.
Special precautions to be taken by the person administering the veterinary medicinal product to Animals.
Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product.

Wash hands thoroughly with soap and water immediately after use of the product.

Use during pregnancy and lactation:
The safety of the veterinary medicinal product in breeding, pregnant and lactating dogs has been demonstrated. Can be used in breeding, pregnant and lactating dogs.

Pharmacodynamics properties:
Pharmacotherapeutic group: Ectoparasiticides for systemic use Fluralaner is an acaricide and insecticide. It is effcacious against ticks (Ixodes spp., Dermacentor spp. and Rhipicephalus sanguineus) and fleas (Ctenocephalides spp.) and mites (Demodex spp., Sarcoptes spp., Otodectes spp.) on the dog Fluralaner has a high potency against ticks and fleas by exposure via feeding, i.e. it is systemically active on target parasites.
Fluralaner is a potent inhibitor of parts of the arthropod nervous system by acting antagonistically on ligand-gated chloride channels (GABA-receptor and glutamate-receptor). In molecular on-target studies on insect GABA receptors of flea and fly, fluralaner is not affected by dieldrin resistance. In in-vitro bio-assays, fluralaner is not affected by proven field resistances against amidines (tick), organophosphates (tick, mite), cyclodienes (tick, flea, fly), macrocyclic lactones (sea lice), phenylpyrazoles (tick, flea), benzophenyl ureas (tick), pyrethroids (tick, mite) and carbamates (tick, mite). Newly emerged fleas on a dog are killed before viable eggs are produced. An in-vitro study also demonstrated that very low concentrations of fluralaner stop the production of viable eggs by fleas. The flea life cycle is broken due to the rapid onset of action and long lasting effcacy against adult fleas on the animal and the absence of viable egg production.

Pharmacokinectics particulars:
Following oral administration, fluralaner is readily absorbed reaching maximum plasma concentrations within 1 day. Food enhances the absorption. Fluralaner is systemically distributed and reaches the highest concentrations in fat, followed by liver, kidney and muscle. The prolonged persistence and slow elimination from plasma (t1/2 = 12 days) and the lack of extensive metabolism provide effective concentrations of fluralaner for the duration of the inter-dosing interval. Individual variation in Cmax and t1/2 was observed. The major route of elimination is the excretion of unchanged fluralaner in faeces (~90% of the dose). Renal clearance is the minor route of elimination.
Interaction with other medicinal products and other forms of interaction: None known.
Fluralaner is highly bound to plasma proteins and might compete with other highly bound drugs such as non-steroidal anti-inflammatory drugs (NSAIDs) and the cumarin derivative warfarin. Incubation of fluralaner in the presence of carprofen or warfarin in dog plasma at maximum expected plasma concentrations did not reduce the protein binding of fluralaner, carprofen or warfarin.

Incompitabilities: None Known

Special Precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product:
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Withdrawal period(s): Not applicable.

Storage: Store below 30°C.
Keep out of sight and reach of Children.

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VETERINARY
NOT FOR HUMAN USE
FOR ANIMAL TREATMENT ONLY

SAVAVET
Shaping the Future

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