Power® Gold

Chewable unit

Chewable tablet for dogs

FOR VETERINARY USE
Prescription medication

Warning: Read this package insert before using the product.
External Antiparasitic - Isoxazolines - Fluralaner

Composition
Fluralaner ..... 13,64 % p/p
Excipients q.s..... 100,00 % p/p

Dosage, route of administration and instructions for use
POWER GOLD is indicated for the treatment and control of fleas and ticks on dogs.
Ticks: *Rhipicephalus sanguineus.*
Fleas: *Ctenocephalides felis. Ctenocephalides canis*
The product is intended for canines, to be administered orally. Administer together with food or immediately after the dog has been fed.

Dose
The chewable tablets must be administered according to the established weight range, to provide a minimum dose of 25 mg/kg of fluralaner.

Indicative dosage table

Fluralaner/unit dose (mg/unit dose)	Number of dosage units to be administered	Weight range (kg)	Dose range (mg/kg)
112,5	1	>2 - 4,5	25 - 56,3
250	1	4,6 - 10	25 - 54,3
500	1	10,1 - 20	25 - 49,5
1000	1	20,1 - 40	25 - 49,8
1400	1	40,1 - 56	25 - 34,9

A single dose of **POWER GOLD** has an activity that persists for 12 weeks.
It can be repeated after these periods at the veterinarian's discretion.

Pharmacological / Immunological Properties
Fluralaner is an acaricide and insecticide belonging to the isoxazoline group.
Isoxazolines act at the central nervous system or the neuromuscular junction of the insect, rather than directly on muscles fibers.
Fluralaner is a potent inhibitor of the arthropod nervous system by acting antagonistically on ligand-regulated chloride channels (GABA receptor and glutamate receptor) and work by blocking pre- and post-synaptic transfer of chloride ions across cell membranes.
This results in uncontrolled activity of the central nervous system and death of insects or acarines.
The binding affinity of fluralaner to receptors of ligand-gated chloride channels was reported significantly lower in mammals than in arthropods.

Pharmacokinetic Properties
After oral administration to dogs, fluralaner appears to be readily absorbed: mean fluralaner Cmax were reached within 1 day (Tmax). Fluralaner plasma concentrations declined over time. Some secondary concentration peaks were detected, that could be explained by enterohepatic re-circulation. After oral and intravenous administration, fluralaner demonstrated a mean apparent half-life (t1/2) of 12 15 days and long mean residence time (MRT) of 15 20 days. Fluralaner plasma concentrations were quantifiable for up to 3 months after oral administration. Systemic exposure increases when fluralaner is administered to fed animals. Once absorbed, fluralaner is well distributed to tissues. The highest concentrations were found in fat, followed by liver, kidney, and muscle. Also, fluralaner was quantifiable in hair and skin. Volume of distribution was found to be moderate (Vz=3 l/kg), and clearance very low (Cl of approx. 0.1 l/kg/h). An in vitro study demonstrated that 100% of fluralaner is bound to plasma proteins in cats and dogs. This high level of protein binding of fluralaner was consistent across different plasma concentrations. Unchanged parent fluralaner was found primarily in feces (approx. 90% of the dose), suggesting that this is the main route of elimination. Renal excretion appears to be a minor route of excretion, with less than approximately 0.001% of the dose found in urine as unchanged fluralaner.

Interactions with Other Drugs
No interactions have been reported to date. However, Fluralaner is highly bound to plasma proteins and could compete with other active substances with high affinity to proteins such as non-steroidal anti-inflammatory drugs (NSAIDs).

Side Effects
Mild and transitory gastrointestinal effects, such as vomiting, diarrhea, inappetence and salivation, may be observed, although uncommon.
Association with seizures and lethargy has rarely been reported.

Administration during Pregnancy and Lactation
POWER GOLD may be administered during pregnancy and lactation.

Contraindications, restrictions and adverse reactions
Do not use in dogs with known sensitivity to fluralaner.
Caution should be exercised in dogs with a known history of epilepsy or epileptiform reactions.
Not recommended in dogs under 8 weeks of age or less than 2 kg of body weight, given that its safety has not been established in these categories.
It is not recommended to repeat the treatment before 8 weeks after the first dose.
The product can be used in pregnant and lactating dogs.
The use of fluralaner has been tested in MRD 1 dogs (P. glycoprotein deficient dogs such as Collies and their crosses) without any inconvenience.

Incompatibilities
None reported.

Overdose and Antidotes
The most common signs observed in cases of overdose have been mild and transient gastrointestinal effects such as diarrhea. vomiting. inappetence and sialorrhea.
No antidotes are known.

User Warnings
Do not drink, smoke, or eat during administration. Wash your hands after application. Avoid contact with eyes and mucous membranes. In case of contact with the eyes, wash with plenty of water. Do not swallow. Do not store together with food. Keep out of the reach of children and pets. In case of accidental or intentional ingestion, wash mouth. Do not induce vomiting and call the Physician. There is no specific antidote; symptomatic treatment is advised.

National Poison Control Center: 0800-333-0160.
IN CASE OF POISONING, SPEAK WITH A PHYSICIAN AND GIVE THEM THIS LABEL

Storage Conditions
Store the product in its original container, protected from direct sunlight. Do not store above 30 °C or in a refrigerator. Do not freeze. The containers are contained for transport in double corrugated cardboard boxes. Used containers should be discarded according to local legislation.

Dosage Form
POWER GOLD is presented in individual boxes with a package insert and blister pack containing:

- 1 chewable unit containing 112.5 mg of fluralaner
- 1 chewable unit containing 250 mg of fluralaner
- 1 chewable unit containing 500 mg of fluralaner
- 1 chewable unit containing 1000 mg of fluralaner
- 1 chewable unit containing 1400 mg of fluralaner

Each chewable unit is light brown to dark brown in color and has a smooth or slightly rough surface and cylindrical shape. Some streaks or specks, or both, may be seen.

senasa - Certificate No. 22-016
Manuf. Plant No. 4384 - Argentine Industry

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