

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

Composition

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

Indications, Route of Administration and Instructions for Use

POWER GOLD 1 MES is prescribed for the treatment and control of fleas and ticks in 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

Chewable tablets must be administered per weight range for minimum dose of 10 mg/kg Fluralaner.

Illustrative dosage table

Fluralaner/unit dose (mg/unit dose)	Number of dosage units to be administered	Weight range (kg)	Dose range (mg/kg)
45	1	>2 - 4,5	10 - 22,5
100	1	4,6 - 10	10 - 22,2
200	1	10,1 - 20	10 - 20
400	1	20,1 - 40	10 - 20
560	1	40,1 - 56	10 - 14

The activity of a single dose of **POWER GOLD 1 MES** persists for 30 days.
It may be readministered after this period upon the veterinarian's discretion.

Pharmacological/Immunological Properties

Fluralaner is an acaricide and insecticide belonging to the Isoxazoline group. Isoxazolines act on the central nervous system at the insect's neuromuscular junction and not directly on muscle 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 chloride channel receptors was reported as significantly lower in mammals than in arthropods.

Pharmacokinetic Properties

After an oral administration in dogs, Fluralaner is readily absorbed; the mean Fluralaner C_{max} was reached within 1 day (T_{max}). Fluralaner plasma concentrations declined over time. Some secondary concentration peaks were detected, that could be explained by enterohepatic re-circulation. After an oral and intravenous administration, Fluralaner showed an apparent half-life (t_{1/2}) of 12-15 days, and a long mean residence time (MRT) of 15-20 days. Fluralaner plasma concentrations were quantifiable for up to 3 months after an oral administration. Systemic exposures increase when Fluralaner is administered in fed animals. Once absorbed, Fluralaner is well distributed among all 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 (V_z=3 l/kg), and clearance very low (Cl of approx. 0.1 l/kg/h). An in vitro study showed that Fluralaner is 100% bound to plasma proteins in cats and dogs. This high level of protein binding of Fluralaner was consistent across different plasma concentrations. Intact 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 <0.001% of the dose found in urine as intact Fluralaner.

Drug Interactions

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

Side Effects

Mild and transitory gastrointestinal effects may occur with a low frequency, such as vomiting, diarrhea, lack of appetite, and salivation. Association with seizures and lethargy has rarely been reported.

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.
The safety of POWER GOLD 1 MES has not been studied in pregnant and lactating female dogs. In these cases, it must be used upon the attending veterinarian's discretion.
Fluralaner has been tested in MRD 1 dogs (P. glycoprotein deficient dogs, such as Collies and crossbreeds) without any issues.

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 sialorrhoea. No antidotes are known.

User Warnings

Do not drink, smoke or eat during administration. Wash your hands after handling. 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 veterinarian. 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 current local legislation.

Dosage Form

POWER GOLD 1 MES comes in individual boxes with a package insert and a blister pack containing:

- 1 chewable tablet with 45 mg Fluralaner
- 1 chewable tablet with 100 mg Fluralaner
- 1 chewable tablet with 200 mg Fluralaner
- 1 chewable tablet with 400 mg Fluralaner
- 1 chewable tablet with 560 mg Fluralaner

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

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BROUWER S.A.

Dr. Rafael Bielsa 232/8 (C1427AZD) Buenos Aires.

Tel.: (+54 911) 4555-6663.

www.brouwer.com.ar