InnoPharma LABORATORIO	**MEDICAL INFORMATION ON VETERINARY PRODUCTS**
	Cis-A-Prid® Cisapride, 5 mg/mL ORAL SUSPENSION

CIS - A - PRID ®

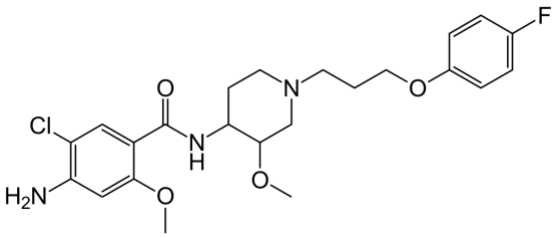
Registration number Q-0666-050

FORMULA:
Each ml contains:
Cisapride Monohydrate equivalent to..... 5 mg
of Cisapride
Vehicle c.b.p..... 1 ml

THERAPEUTIC INDICATIONS

Cis - A - Prid ®, is indicated for the prophylactic and therapeutic treatment of upper digestive tract disorders such as vomiting, nausea, esophagitis, gastritis, puppy pylorospasm, idiopathic megaesophagus, gastric volvulus, constipation, paralytic ileus, and postoperative paralytic ileus.

Cisapride is a 5HT4 receptor agonist piperidyl benzamide-type drug that increases adenylate cyclase within neurons, thereby stimulating gastrointestinal motility.



PHARMACOKINETICS
After oral administration, absorption of cisapride is rapid. Oral bioavailability: in cats, dogs, horses, and humans, appears to be low to moderate (30 to 60%). This is generally attributed to extensive first-pass metabolism in the intestinal wall or liver of many species. Peak plasma levels are reached within 1 to 2 hours, and the elimination half-life is 10 hours. The presence of food favors the rate of absorption Cisapride is extensively metabolized by oxidative N-dealkylation and aromatic hydroxylation. The excretion of its metabolites is 75% excreted in bile and the remaining 25% in urine. Excretion in breast milk is very limited. Cisapride is extensively bound to plasma proteins (97.5%). The highest plasma concentration occurs between one and four hours after oral administration and the highest tissue concentration is in the colon.

PHARMACODYNAMICS
Agonist and antagonist of serotonergic receptors of the digestive tract, as it is an agonist against 5-ht4 receptors and antagonist of 5-ht3 receptors, increases gastric and antroduodenal peristaltic activity, small and large intestine motility because it stimulates the release of acetylcholine in the postganglionic nerve

endings of the myenteric plexus, without affecting cholinesterase activity, thereby promoting motility of the gastrointestinal tract. Although cisapride structurally resembles metoclopramide, it lacks its antidopaminergic effects, thus producing fewer extrapyramidal effects.
In dogs, cisapride increases digestive motility and gastroduodenal coordination, accelerates gastric emptying, increases propulsive contractions of the small and large intestines, and decreases intestinal transit time. Cisapride does not induce muscarinic or nicotinic receptor stimulation or inhibit acetylcholinesterase activity. Cisapride does not possess dopaminergic receptor-blocking properties at therapeutic doses. Cisapride is specifically distributed in intestinal and gastric tissues.

CONTRAINDICATIONS
Do not administer in equines and domestic leporidae (rabbits) destined for human consumption. Do not administer in case of paralysis due to obstruction and in cases of stomach torsion. Cis-A Prid is not indicated to control uremic vomiting or motion sickness. It should not be used as a preventive in animals that will undergo anastomotic surgery of the gastrointestinal tract. Do not use in animals with perforation or hemorrhage of the gastrointestinal tract. In case of overdose, administer atropine sulfate and activated charcoal. There is no evidence of embryotoxic or teratogenic effects.

ADVERSE EFFECTS
Cisapride is safe in felines at recommended doses. Vomiting, diarrhea, and abdominal pain may occur. Rare cases of prolonged QT intervals or other cardiac arrhythmias have been reported, in animals, there have been no reports of the development of cardiac arrhythmias. It may be necessary to decrease the dose in patients with severe hepatic insufficiency.

Oral lethal dose LD50
Rats-4155 mg/kg.
Mice: 1280 mg/kg.
Rats, neonatal: 160 mg/kg.

DRUG INTERACTIONS
Antimuscarinic anticholinergics and opioid analgesics antagonize the effect of cisapride; histamine H2 antagonists, such as cimetidine and ranitidine, increase the bioavailability of the drug. Cisapride increases the absorption rate and decreases the bioavailability of cimetidine and ranitidine. Administration with ketoconazole, itraconazole, miconazole, erythromycin, and clarithromycin inhibits their biotransformation, increasing the risk of toxic effects.

PRECAUTIONS AND RELATIONSHIP WITH CARCINOGENESIS, MUTAGENESIS, TERATOGENESIS, AND FERTILITY EFFECTS.

Its use during pregnancy should occur only when the benefits outweigh the risks.
At recommended doses, there is no evidence of embryotoxic or teratogenic effects.
The amount of cisapride excreted in breast milk is minimal, however, it is recommended to use it with caution in nursing mothers.

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ROUTE OF ADMINISTRATION
Oral.
It is recommended to administer 30 minutes before ingesting any food.
Each ml is equivalent to 20 drops and contains 5 mg of Cis A Prid.

DOSE
Canines and domestic felines: The recommended dose of Cisapride is 1 mg/kg of body weight, equivalent to 1 ml of Cis-A-Prid for each 5 kg of body weight,
Domestic equines: The recommended dose of Cisapride is 0.1 to 0.5 mg/kg body weight, equivalent to 1 ml of Cis-A-Prid for 10 to 50 kg body weight.
Domestic Leporidae (rabbits): It is recommended to administer 0.125 to 0.5 mg Cisapride per kg body weight, equivalent to 1 to 4 drops/kg body weight.
The administration interval is every 8 to 12 hours.
Colts: in peripartum asphyxia, the total dose of 2 ml, equivalent to 10 mg per animal, every 6 to 8 hours, until the functionality of the gastrointestinal tract is restored.

The duration of treatment is 1 to 5 days, depending on the general condition of the patient, clinical evaluations, and at the discretion of the Veterinarian.

PRESENTATION
Box with 20 ml bottle
Shake before administration

WARNINGS
Do not administer in equines and domestic leporidae (rabbits) intended for human consumption.
Store in a dry and cool place at no more than 30ºC (86ºF).
Protect from light.
Keep out of reach of children and domestic animals.
Consult a Veterinarian Doctor.
PRODUCT OF EXCLUSIVE USE IN VETERINARY MEDICINE.

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