InnoPharma LABORATORIO	**MEDICAL INFORMATION ON VETERINARY PRODUCTS**
	INNOPRAMID GOTAS Metoclopramide Hydrochloride 5 mg / mL ORAL SOLUTION

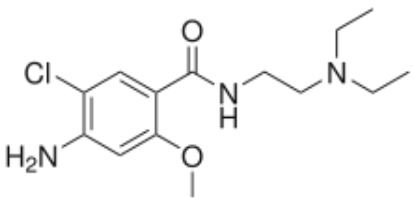
INNOPRAMID GOTAS

Registration Number Q-0666-016
Antiemetic

FORMULA:
Each mL contains:
Metoclopramide Hydrochloride 5mg.
Vehicle q.s. 1mL

THERAPEUTIC INDICATIONS

Prokinetic and Antiemetic, it has an antidopaminergic D2 action and is also an agonist of the 5-HT4 receptors for serotonin, so it is recommended in dogs and cats that present intestinal motility alterations, it allows the relaxation of sphincters such as the pylorus, as well as the movement of intestinal loops, nausea and vomiting of central and/or peripheral origin associated to surgical procedures, metabolic or infectious diseases and occasionally associated with drugs.



Metoclopramide is a derivative of para-aminobenzoic acid; structurally related to procaineamide, although it lacks significant antiarrhythmic and local anesthetic actions. Most of its effects occur in the CNS as a consequence of dopaminergic blockade. The effects of metoclopramide are partially due to its activity as a dopamine antagonist, the gastric prokinetic properties are due both to the antagonism of gastric dopamine receptors and to the increased release of acetylcholine, adding mixed properties on serotonergic 5HT3 or M receptors. It is a dopaminergic antagonist capable of blocking gastrointestinal effects caused by local or general administration of dopaminergic agonists. In the gastrointestinal tract, metoclopramide increases smooth muscle motility (inhibiting smooth muscle relaxation produced by dopamine) from the esophagus to the proximal part of the small intestine, accelerates gastric emptying and intestinal transit from the duodenum to the ileocecal valve. It decreases receptive relaxation in the upper part of the stomach and increases motility of the upper gastrointestinal tract, without modifying pancreatic, biliary or gastric secretions.Therefore; the effects combine to accelerate gastric emptying and reduce the backflow from duodenum and stomach to esophagus; by increasing the resting pressure of the lower esophageal sphincter and the amplitude of peristaltic contractions; which justifies its use as a prokinetic and antiemetic agent.

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PHARMACOKINETICS AND PHARMACODYNAMICS:

Metoclopramide is an antiemetic, prokinetic. It belongs to the orthopramide group. At central level it acts by blocking D2 Dopamine receptors in the chemoreceptor trigger area interfering with the integration of afferent emetogenic impulses. At peripheral level, the blockade of D2 receptors produces an increase in intestinal peristalsis (prokinetic effect), which is enhanced by acting as an indirect cholinergic, facilitating the release of acetylcholine by intestinal postganglionic neurons. Oral intramuscular bioavailability undergoes notable interindividual variations.
Intramuscular route is 74.96%. Oral absorption is rapid and practically complete. The precise time for action to appear is 1-3 min IV, 10-15 min IM and 30-60 min Oral. Duration of action is 1-2 hours. The degree of binding to plasma proteins is 13-30 %. Metabolized with small amount, it is eliminated in urine in unaltered and metabolized form, approximately 5% is excreted in feces.

PHARMACOKINETICS AND PHARMACODYNAMICS:

The onset of pharmacological action of metoclopramide is 1 to 3 minutes after intravenous administration, 10 to 15 minutes after oral administration. The pharmacological effects persist for one to two hours. The absolute oral bioavailability of metoclopramide is 80%. Peak plasma concentrations occur about 1 to 2 hours after a single oral dose; peak concentrations increase linearly. The average elimination half-life in individuals with normal renal function is 5 to 6 hours. This drug does not bind extensively to plasma proteins; corresponding studies suggest extensive distribution of this drug in body tissues.

Bioavailability in IM application is 74 to 96%.

Distribution Distributed in all tissues and body fluids including CNS only 13 to 22% bound to proteins Metoclopramide crosses the placental barrier and is also distributed in milk.

Elimination: Plasma concentrations decline in a biphasic manner. Although data from single dose studies are limited, they suggest that the elimination of metoclopramide is dose-dependent. Its half-life in dogs is 90 minutes. The major metabolite found in urine is 2-[(4-amino-5-chloro-2-methoxybenzoyl) amino] acetic acid. It is not yet known whether this metabolite is pharmacologically active. Metoclopramide is conjugated with sulfuric and/or glucuronic acid. Metoclopramide and its metabolites are excreted in urine and feces.

DRUG INTERACTIONS:

Certain interactions of metoclopramide have been reported in patients as anesthetics, atropine or opioids decreases its effect, favors the absorption of drugs in the intestine such as cyclosporine, tetracyclines among others. It can potentiate drugs such as phenothiazines and butyrophenones (neuroleptics such as droperidol).

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TOXICITY AND ANTIDOTE:
The likely clinical cyphers of overdosage are extrapyramidal signs including sedation, ataxia, agitation, nausea, vomiting, and constipation. There is no specific antidote therapy for metoclopramide poisoning. If an oral ingestion is recent, the stomach should be emptied using standard protocols. Anticholinergic agents (diphenhydramine 2.2 mg/kg IV, benztropine, etc.) that enter the CNS may be useful in controlling extrapyramidal effects.

Overdosage (symptoms, emergency measures, antidotes) Most of the clinical signs recorded after overdosage are well known extrapyramidal side effects (see section Adverse reactions). In the absence of a specific antidote, it is recommended to offer a calm environment to the animals until the extrapyramidal side effects disappear. Metoclopramide is rapidly metabolized and eliminated, side effects usually disappear quickly.

WARNINGS:
Do not use if stimulation of gastrointestinal motility may be dangerous; for example, in the presence of gastrointestinal bleeding, mechanical obstruction or perforation.
It is contraindicated in patients with pheochromocytoma, since the drug may cause hypertensive crises, probably associated with the release of catecholamines by the tumor.
It is contraindicated in patients with known sensitivity and intolerance to the drug; it should not be used in epileptic patients, or who are being administered other drugs that may cause extrapyramidal reactions, characterized by movements and muscle control problems.
Keep this product out of the reach of children and pets.

DOSAGE AND ROUTE OF ADMINISTRATION:
0.4 - 0.6 mg/kg, every 6-8 hours.

USE IN:
Domestic canines and felines.

PRESENTATION:
Dropper bottle with 25 mL.

STORAGE RECOMMENDATIONS:
Keep in a cool, dry place.
Protect from light.
Consult the Veterinarian Doctor.

PRODUCT FOR EXCLUSIVE USE IN VETERINARY MEDICINE.

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