DICYCLOVERINE HCl

RELESTAL®

5 mg/mL Syrup (Oral Drops)
10 mg/5 mL Syrup

Anticholinergic/Antispasmodic

FORMULATIONS
Each mL syrup (oral drops) contains:
Dicycloverine hydrochloride..... 5 mg
Each 5 mL (1 teaspoonful) syrup contains:
Dicycloverine hydrochloride.....10 mg

PHARMACOLOGY
Dicycloverine hydrochloride (**RELESTAL®**) acts as a nonselective smooth muscle relaxant by:
1) a specific anticholinergic effect at the acetylcholine-receptor sites and
2) acting directly on the bradykinin-and histamine-induced spasm. Dicycloverine has little or no effect on gastric secretion.

PHARMACOKINETICS
Dicycloverine hydrochloride is absorbed rapidly from the gastrointestinal tract, achieving peak plasma concentrations within 1 to 1.5 hours after oral administration. Extensive tissue distribution is evident by its apparent volume of distribution which is 3.65 L/kg.

Plasma concentrations of Dicycloverine decline in a biphasic manner. The half-life of Dicycloverine in the initial distribution phase is about 1.8 hours and the half-life in the terminal elimination phase is about 9-10 hours. About 80% of a dose of Dicycloverine is eliminated in urine and about 10% in feces.

INDICATIONS
For the treatment of functional disturbances of gastrointestinal tract motility such as irritable bowel syndrome and renal and biliary colic. As with other antispasmodics, Dicycloverine has limited efficacy in the treatment of these disorders and should be used only if other measures (e.g diet) have been of little or no benefit. Dicycloverine has been used alone or in combination with phenobarbital in the treatment of infant colic and acute enterocolitis but lacks substantial evidence of efficacy in these conditions. Infant colic is considered a benign and self-limiting condition.

DOSAGE AND ADMINISTRATION
Administer orally every 4 to 6 hours.

Age	Oral Drops	Syrup
Infants 6 months to 2 years	0.5 to 1 mL	
Children 2 to 5 years 6 to12 years		2.5 to 5 mL (1/2 to 1 teaspoonful) 5 mL (1 teaspoonful)

Or as prescribed by the physician.

CONTRAINDICATIONS
Should not be given to patients with obstructive uropathy, obstructive disease of the GI tract, ulcerative colitis, reflux esophagitis, hypersensitivity to Dicycloverine hydrochloride, and nursing mothers.

PRECAUTIONS
Administer with caution to patients with hepatic or renal disease, hyperthyroidism, hypertension, known or suspected prostatic hypertrophy, and hiatal hernia.

WARNINGS
Fever and heat stroke due to decreased sweating may be experienced in the presence of high environmental temperature.

Dicycloverine hydrochloride may produce drowsiness or blurred vision.

A physician should be consulted before administering Dicycloverine hydrochloride to infants below six months. Dicycloverine hydrochloride may cause serious respiratory symptoms (dyspnea, shortness of breath, breathlessness, respiratory collapse, apnea, asphyxia), seizures, syncope, pulse rate fluctuations, muscular hypotonia and coma.

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY
RELESTAL® 5 mg/mL Syrup (Oral Drops) - in bottle of 15 mL
RELESTAL® 10 mg/5mL Syrup - in bottle of 60 mL

ALWAYS KEEP CONTAINER TIGHTLY CLOSED/STORE AT TEMPERATURES NOT EXCEEDING 30° C

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Manufactured by Amherst Laboratories, Inc.
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