Guard against further absorption of the drug—use lavage, cathartics and/or enemas.

Combat peripheral anticholinergic effects (residual dry mouth, etc.)—utilize a quaternary ammonium cholineesterase, such as neostigmine methylsulfate i.m. or p.o., metaraminol i.v., and supportive care.

Combat respiratory depression—administer oxygen; a respiratory stimulant such as Dopram® i.v.; artificial respiration.

**Use and Administration:** The dosage of Robinul or Robinul Forte should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. The presently recommended maximum daily dosage of glycopyrrolate is 8 mg.

Robinul (glycopyrrolate, 1 mg) tablets. The recommended initial dosage of Robinul for adults is one tablet three times daily (in the morning, early afternoon, and at bedtime). Some patients may require two tablets at bedtime to assure overnight control of symptoms. For maintenance, a dosage of one tablet twice a day is frequently adequate.

Robinul Forte (glycopyrrolate, 2 mg) tablets. The recommended dosage of Robinul Forte for adults is one tablet two or three times daily at equally spaced intervals.

Robinul tablets are not recommended for use in children under the age of 12 years.

**Drug Interactions:** There are no known drug interactions.

**How Supplied:** Robinul (glycopyrrolate, 1 mg) tablets in bottles of 100 (NDC 0031-7624-43) and 500 (NDC 0031-7624-70).

Robinul Forte (glycopyrrolate, 2 mg) tablets in bottles of 100 (NDC 0031-7640763).

Rev. February 1985

A.H. ROBINS COMPANY
RICHMOND, VA 23220

12-827
S-34
7-16-85

PHARMACEUTICAL DIVISION
A.H. ROBINS COMPANY
RICHMOND, VA 23220

Rev. February 1985
Cone to the treatment of systemic disease, such as rheumatoid arthritis and inflammatory bowel disease.

**Contraindications:**
- Glaucoma
- Obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy)
- Obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.)
- Paralytic ileus
- Intestinal atony of the elderly or debilitated patient
- Unstable cardiovascular status in acute hemorrhage
- Severe ulcerative colitis
- Toxic megacolon complicating ulcerative colitis
- Myasthenia gravis

**Robinul (glycopyrrolate):**
- Tablets are contraindicated in those patients with a hypersensitivity to glycopyrrolate.
- **Warnings:** In the presence of a high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with use of Robinul.

**Diarrhea:**
- May be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

**Robinul (glycopyrrolate):**
- May produce drowsiness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery, or performing hazardous work while taking this drug.
- Theoretically, with overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis.

**Pregnancy:**
- The safety of this drug during pregnancy has not been established. The use of any drug during pregnancy requires that the potential benefits of the drug be weighed against possible hazards to mother and child. Reproduction studies in rats revealed no teratogenic effects from glycopyrrolate; however, the potent anticholinergic action of this agent resulted in diminished rates of conception and survival of the offspring. Other studies in dogs suggest that this may be due to diminished seminal secretion which is evident at high doses of glycopyrrolate.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

**Pediatric Use:** Since there is no adequate experience in children who have received this drug, safety and efficacy in