INDICATIONS AND USAGE: Cromolyn Sodium Oral Solution, Concentrate is indicated in the management of patients with mastocytosis. Use of this product has been associated with improvement in epigastric distress, headaches, flushing, pruritus, urticaria, abdominal pain, nausea, and itching in some patients.

CONTRAINDICATIONS: Cromolyn Sodium Oral Solution, Concentrate is contraindicated in those patients who have shown hypersensitivity to cromolyn sodium.

WARNINGS: The recommended dosage should be decreased in patients with decreased renal or hepatic function. Severe anaphylactic reactions may occur rarely in association with cromolyn sodium administration.

PRECAUTIONS: In view of the biliary and renal routes of excretion of Cromolyn Sodium Oral Solution, Concentrate, consideration should be given to decreasing the dosage of the drug in patients with impaired renal or hepatic function.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In carcinogenicity studies in mice, hamsters, and rats, cromolyn sodium had no neoplastic effects at intraperitoneal doses up to 150 mg/kg three days per week for 12 months in mice, at intraperitoneal doses up to 53 mg/kg three days per week for 15 weeks followed by 17.5 mg/kg three days per week for 37 weeks in hamsters, and at subcutaneous doses up to 75 mg/kg six days per week for 18 months in rats. These doses in mice, hamsters, and rats are less than the maximum recommended daily oral dose in adults on a mg/m² basis.

Cromolyn sodium showed no mutagenic potential in Ames Salmonella/microsome plate assays, rifiloto gene conversion in Saccharomyces cerevisiae and in an in vitro cytogenetic study in human peripheral lymphocytes. In rats, cromolyn sodium showed no evidence of impaired fertility at subcutaneous doses up to 175 mg/kg in males (approximately equal to the maximum recommended daily oral dose in adults on a mg/m² basis) and 164 mg/kg in rats (less than the maximum recommended daily oral dose in adults on a mg/m² basis) or at intravenous doses up to 485 mg/kg in rabbits (approximately 4 times the maximum recommended daily oral dose in adults on a mg/m² basis). There are, however, no adequate and well controlled studies in pregnant women.

Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Drug Interaction During Pregnancy: In pregnant mice, cromolyn sodium at a subcutaneous dose of 540 mg/kg or at intraperitoneal doses up to 485 mg/kg (approximately equal to the maximum recommended daily oral dose in adults on a mg/m² basis) or at intravenous doses up to 485 mg/kg in rabbits (approximately 4 times the maximum recommended daily oral dose in adults on a mg/m² basis) was added to isoprenaline at a subcutaneous dose of 2.7 mg/kg. No such interaction was observed in rats or rabbits.
Cromolyn Sodium Oral Solution, Concentrate

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Cromolyn Sodium Oral Solution, Concentrate is administered to a nursing woman.

Pediatric Use: In adult rats no adverse effects of cromolyn sodium were observed at oral doses up to 6144 mg/kg (approximately 9 times the maximum recommended daily oral dose in adults on a mg/m² basis). In neonatal rats, cromolyn sodium increased mortality at oral doses of 1000 mg/kg or greater (approximately 9 times the maximum recommended daily oral dose in infants on a mg/m² basis) but not at doses of 300 mg/kg or less (approximately 3 times the maximum recommended daily oral dose in infants on a mg/m² basis). Plasma and kidney concentrations of cromolyn after oral administration to neonatal rats were up to 20 times greater than those in older rats. In term infants up to six months of age, available clinical data suggest that the dose should not exceed 20 mg/kg/day. The use of this product in pediatric patients less than two years of age should be reserved for patients with severe disease in which the potential benefits clearly outweigh the risks.

Geriatric Use: Clinical studies of Cromolyn Sodium Oral Solution, Concentrate did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS: Most of the adverse events reported in mastocytosis patients have been transient and could represent symptoms of the disease. The most frequently reported adverse events in mastocytosis patients who have received Cromolyn Sodium Oral Solution, Concentrate during clinical studies were headache and diarrhea, each of which occurred in 4 of the 87 patients. Pruritis, nausea, and myalgia were each reported in 3 patients and abdominal pain, rash, and irritability in 2 patients each. One report of malaise was also recorded.

Other Adverse Events: Additional adverse events have been reported during studies in other clinical conditions and from worldwide postmarketing experience. In most cases the available information is incomplete and attribution to the drug cannot be determined. The majority of these reports involve the gastrointestinal and cutaneous systems and include diarrhea, nausea, abdominal pain, constipation, dyspepsia, flatulence, glossitis, stomatitis, vomiting, dysphagia, esophagospasm, and other less commonly reported events (the majority representing only a single report) including the following:

- Skin: pruritis, rash, urticaria/angiodyema, erythema/burning, photosensitivity
- Musculoskeletal: arthralgia, myalgia, stiffness/weakness of legs
- Neurologic: headache, dizziness, hypoesthesia, paresis, tremor, myalgia, migraine, convulsions, flushing
- Psychiatric: psychosis, anxiety, depression, hallucinations, behavior change, insomnia, nervousness
- Heart Rate: tachycardia, premature ventricular contractions (PVCs), palpitations
- Respiratory: pharyngitis, dyspnea

Miscellaneous: fatigue, edema, unpleasant taste, chest pain, postural lightheadedness and lethargy, dysuria, urinary frequency, purpura, hepatic function test abnormal, polyosystemia, neutropenia, pancytopenia, tinnitus, lupus erythematosus (LE) syndrome

DOSE AND ADMINISTRATION: NOT FOR INHALATION OR INJECTION. SEE DIRECTIONS FOR USE.

The usual starting dose is as follows:

- Adults and Adolescents (13 Years and Older): Two ampules four times daily, taken one-half hour before meals and at bedtime.
- Children 2-12 Years: One ampule four times daily, taken one-half hour before meals and at bedtime.
- Pediatric Patients Under 2 Years: Not recommended.

If satisfactory control of symptoms is not achieved within two to three weeks, the dosage may be increased but should not exceed 40 mg/kg/day. Patients should be advised that the effect of Cromolyn Sodium Oral Solution, Concentrate therapy is dependent upon its administration at regular intervals, as directed.

Maintenance Dose: Once a therapeutic response has been achieved, the dose may be reduced to the minimum required to maintain the patient with a lower degree of symptomatology. To prevent relapses, the dosage should be maintained.

Administration: Cromolyn Sodium Oral Solution, Concentrate should be administered as a solution at least 1/2 hour before meals and at bedtime after preparation according to the following directions:

1. Break open ampule(s) and squeeze liquid contents of ampule(s) into a glass of water.
2. Stir solution.
3. Drink all of the liquid.

HOW SUPPLIED: Cromolyn Sodium Oral Solution, Concentrate is supplied as an unpreserved, colorless solution supplied in a low density polyethylene plastic unit dose ampule with 8 ampules per foil pouch. Each 5 mL ampule contains 100 mg cromolyn sodium, USP, in purified water.

NDC 16571-150-70 96 ampules x 5 mL
(12 pouches x 8 ampules)

Cromolyn Sodium Oral Solution, Concentrate should be stored between 2° – 25°C (68° – 77°F) (see USP Controlled Room Temperature) and protected from light. Do not use if it contains a precipitate or becomes discolored. Keep out of the reach of children.

Store ampules in foil pouch until ready for use.

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