The empirical formula is C₂₃H₁₄Na₂O₁₁; the molecular weight is 512.34. Its chemical structure is:

Chemically, cromolyn sodium is disodium 5,5’-[(2-hydroxy-bis(trimethylene) dioxy)[bis(4-oxo-4H-1-benzopyran-2-carboxylate)]. The empirical formula is C₁₄H₁₄Na₂O₁₁; the molecular weight is 512.34. Its chemical structure is:

Cromolyn sodium is not a vasoconstrictor, antihistamine, or glucocorticoid activity. Cromolyn sodium has no intrinsic vasocastic, antihistamine, or glucocorticoid activity.

Cromolyn sodium is poorly absorbed from the gastrointestinal tract. No more than 1% of an administered dose is absorbed by humans after oral administration, the remainder being excreted in the feces. The urinary excretion of cromolyn sodium was seen after oral administration of 500 mg by mouth to each of 12 volunteers. From 0.26 to 0.50% of the administered dose was recovered in the first 24 hours of urinary excretion in 3 subjects. The mean urinary excretion of an administered dose over 24 hours in the remaining 9 subjects was 0.45%.

Cromolyn sodium is disodium 5,5’-[(2-hydroxy-bis(trimethylene) dioxy)[bis(4-oxo-4H-1-benzopyran-2-carboxylate)].

It is intended for oral use. Sodium Oral Solution, Concentrate is clear, colorless, and sterile. Having little odor. It may leave a slightly bitter aftertaste. Cromolyn sodium was seen with Cromolyn Sodium Oral Solution, Concentrate.
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 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 67 patients. Pruritus, nausea, and myalgia were each reported in 3 patients and abdominal pain, rash, and intractability in 2 patients each. One report of anaphylaxis 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 system and include: diarrhea, nausea, abdominal pain, constipation, abdominal distention, flatulence, glossitis, stomatitis, vomiting, dysphagia, esophagospasm.

Other less commonly reported events (the majority representing only a single report) include the following:

Skin: pruritus, rash, urticaria/angioedema, erythema/flushing, photosensitivity
Musculoskeletal: arthralgia, myalgia, stiffness/weakness of legs
Neurologic: headache, dizziness, hypoesthesia, paraesthesia, myalgia, 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, postprandial lightheadedness and flushing, dysphagia, upper respiratory tract infection, abdominal pain, weight gain, dyspepsia, meningitis, leukopenia, allergic reactions, arthralgia, panhypopituitarism, myalgia, lupus erythematosus (LE) syndrome

DOSEAGE 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 1.0 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 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 16571-600-96 96 ampules x 5 mL (12 pouches x 8 ampules)
Cromolyn Sodium Oral Solution, Concentrate should be stored between 20° – 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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Manufactured by:
Catalent Pharma Solutions, LLC
Woodstock, IL 60098 USA
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Directions for Use:

1. Open foil pouch by tearing the serrated edge as shown.
2. Remove ampule(s) from the strip.
3. Open the ampule by twisting off the tabbed top section.