CROMOGLICICATO DE SÓDIO
Antiasmático e antialérgico
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DESCRIÇÃO
Antiasmático profilático, antialérgico e anti-inflamatório não esteroidal.

MECANISMO DE AÇÃO
O Cromoglicato de sódio estabiliza a membrana dos mastócitos e impede a ativação e liberação dos mediadores químicos envolvidos na reação alérgica, sendo utilizados no tratamento preventivo, além de diminuir a degranulação dos mastócitos. Inibe também a entrada de cálcio na célula, assim como diminui sua disponibilidade intracelular e, por consequência, diminui a liberação de histamina.

INDICAÇÕES
- Sensibilização a alimentos, mastocitose e dermatite herpetiforme;
- Controla espirros, rinorréia e prurido;
- Tratamento preventivo de rinites e bronquites alérgicas.

DOSE USUAL
Recomendação de 200mg de Cromoglicato de sódio, 3 a 4 vezes ao dia em adultos; 100mg de Cromoglicato de sódio, 3 a 4 vezes ao dia, via oral em crianças acima de 2 anos e de 20mg/kg de Cromoglicato de sódio, divididos em 3 a 4 tomadas, dia para crianças menores de 2 anos.
Recomendação de 2 a 4% sob a forma de instilação nasal, 4 a 6 vezes ao dia em adultos.

SUGESTÕES DE FÓRMULAS

<table>
<thead>
<tr>
<th>Material</th>
<th>Quantidade</th>
</tr>
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<tbody>
<tr>
<td>Cromoglicato Dissódico</td>
<td>100mg</td>
</tr>
<tr>
<td>Solução Oral Qsp.</td>
<td>5 ml</td>
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<td><strong>Modo de Uso:</strong></td>
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<tr>
<td>crianças maiores de 2 anos, utilizar 100mg, 3 a 4 vezes ao dia.</td>
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PRINCIPAIS REFERÊNCIAS
Oral cromolyn sodium in comparison with elimination diet in the irritable bowel syndrome, diarrheic type.

Multicenter study of 428 patients.

BACKGROUND: In a significant number of patients affected by the irritable bowel syndrome, an adverse reaction to food is proposed to be a causative factor. A diet that eliminates the offending foods is the obvious treatment for such adverse reactions. Compliance with a dietetic regimen is often poor and sometimes not completely free from risks.

METHODS: Since the diarrheic type of irritable bowel syndrome seems mainly affected by food intolerance, and previous observations suggested that oral cromolyn sodium is effective in such patients, a multicenter therapeutic trial in the diarrheic type of irritable bowel syndrome was carried out in 346 of 409 patients with this disease, to evaluate the effects of oral cromolyn sodium and compare its efficacy with that of an elimination diet.

RESULTS: Symptoms related to the irritable bowel syndrome improved in 60% of patients treated with elimination diet and in 67% of those treated with oral cromolyn sodium (1500 mg/day) for 1 month. Moreover, in both groups clinical results were significantly better in the patients positive to the skin prick test than in the negative ones.

CONCLUSIONS: These results confirm the high prevalence of adverse reactions to foods in diarrheic irritable bowel syndrome and the usefulness of cromolyn sodium treatment in these patients.

Efficacy and patient satisfaction with cromolyn sodium nasal solution in the treatment of seasonal allergic rhinitis: a placebo-controlled study.

Background: Because the symptoms of seasonal allergic rhinitis are readily recognizable, many individuals self-medicate with nonprescription agents. The mast-cell stabilizer cromolyn sodium is available for over-the-counter (OTC) use in the prevention and treatment of allergic rhinitis.

Objective: The goal of the study was to evaluate the efficacy of cromolyn sodium 4% nasal solution for the treatment of allergic rhinitis in self-selected patients in a nonprescription setting. A secondary objective was to determine whether the instructions and warnings in the OTC labeling provide adequate information for safe and proper OTC use.

Methods: This 2-week, multicenter study had a randomized, double-blind, placebo-controlled, parallel-group design. Advertisements were used to identify allergy sufferers who used OTC products but had not used OTC allergy medications within 48 hours of study entry and did not require prescription medications to control allergy symptoms. Enrolled patients were randomized to receive either cromolyn sodium 4% nasal solution in a metered-spray bottle containing 200 doses or an identical-appearing placebo.

They were instructed to follow the directions for use on the label: that is, to administer 1 spray in each nostril every 4 to 6 hours, no more than 6 times per day, for the prevention or relief of symptoms. Daily use of study drug and concomitant medications was recorded in patient diaries. Patients also rated symptom severity, symptom relief, medication efficacy, and helpfulness of the label instructions. Relief of overall and individual rhinitis symptoms was assessed at the end of weeks 1 and 2.

Results: The intent-to-treat population consisted of 1150 patients (580 cromolyn sodium, 570 placebo). Cromolyn sodium provided greater relief than placebo on all efficacy measures and was statistically significantly more effective than placebo in controlling allergy symptoms ($P = 0.02$), providing overall symptom relief ($P = 0.02$), and relieving sneezing ($P = 0.01$) and nasal congestion ($P = 0.03$). The instructions for use were rated helpful to extremely helpful by >92% of patients, although only ~48% of patients used the drug according to the label instructions. The most common adverse events in both groups were headache and rhinitis, and there was no significant difference in the rates of such events between groups.

Conclusion: In this study, cromolyn sodium 4% nasal solution was well tolerated and effective, suggesting that it is suitable for OTC use in the treatment of seasonal allergic rhinitis.
A large-scale multicenter investigation was undertaken in 3 cities with comparable pollen seasons and atmospheric pollen concentrations in order to obtain more definite information about the safety and efficacy of cromolyn sodium in the treatment of pollen-induced seasonal rhinitis. The 9-wk double-blind study was conducted in 104 patients in Pittsburgh, Pa., Cleveland, Ohio, and Louisville, Ky., during the 1975 ragweed season. It indicated that a nebulized 4% aqueous solution of cromolyn sodium is effective in reducing sneezing, rhinorrhea, nasal congestion, and ocular irritation in ragweed hay fever patients. The efficacy of the drug was notable despite the fact that patients used an average of 52 mg instead of the recommended 62.4 mg daily. Cromolyn sodium did not appear to have a significant effect on transseasonal antiragweed IgE (IgEAR) levels. Patients acceptance of the cromolyn nasal solution was good, and there were no significant adverse reactions. The side effects, which were distributed equally between the drug and placebo groups, were mild and of limited duration.

Comparison of intranasal cromolyn sodium, 4%, and oral terfenadine for allergic rhinitis: symptoms, nasal cytology, nasal ciliary clearance, and rhinomanometry.

Topical intranasal cromolyn sodium, 4% solution, and oral terfenadine, 60 mg tablets, both relieve symptoms of allergic rhinitis with few or no adverse effects, but no comparison of their relative efficacy has been reported. In this double-blind, double-dummy study, 79 patients, ages 12-56 years with symptoms of allergic rhinitis, were randomized to receive either active cromolyn sodium, 1 spray in each nostril QID, or active terfenadine BID along with the appropriate placebo spray or tablet for 4 weeks following a 1-week baseline qualification period. Patients' daily symptom scores were reviewed weekly and constituted the primary efficacy measures. Changes in nasal cytology, nasal ciliary clearance, and rhinomanometry were also assessed. The presence of adverse effects and the overall score of medication efficacy at the end of each week was recorded. The cromolyn sodium and terfenadine groups had comparable baseline scores for severity of allergic rhinitis symptoms and both treatments resulted in significant improvement (P less than.0001) with no statistical difference between them for total symptom scores at the end of 4 weeks. Eosinophils in nasal samples were decreased significantly in the cromolyn treated group with no significant change in the terfenadine-treated group. There were no significant differences between treatment groups in ciliary clearance or rhinomanometry. Adverse effects were uncommon and mild. We conclude that cromolyn sodium and terfenadine are comparably effective and well accepted treatments for allergic rhinitis.

REFERÊNCIAS


