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PRESCRIPTION COMPOUNDING FOR

GENERAL PRACTICE

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HYPERHIDROSIS

The following clinical papers examined whether topical glycopyrrolate could be an effective and safe treatment for differing forms of hyperhidrosis.


ABSTRACT: “Compensatory sweating after sympathectomy does not have a satisfactory, free-of-secondary-effects treatment. Glycopyrrolate has been successfully used to treat other types of hyperhidrosis. Compensatory sweating after sympathectomy could respond to the topical application of glycopyrrolate. Ten patients were selected with compensatory sweating after sympathectomy. One milliliter of a 2% water solution of topical glycopyrrolate was applied once a day over the affected area and massaged for 30 seconds. Treatment was maintained for 6 weeks. The results were rated using a scale from 1 to 10 of satisfaction at the end of the study. Eight of the 10 treated patients dramatically improved with the topical application of glycopyrrolate. Two patients quit the treatment due to secondary effects (accommodative failure and dry mouth). The results of the study demonstrated that local application of glycopyrrolate might be the treatment of choice for compensatory hyperhidrosis.” PMID: 18844718


BACKGROUND: Facial hyperhidrosis may negatively impact the quality of life. Although various conservative modalities have been suggested, the condition is not often treated successfully.

OBJECTIVES: To examine whether topical glycopyrrolate could be an effective and safe treatment for facial hyperhidrosis.

METHODS: Twenty-five patients with facial hyperhidrosis were enrolled and treated with 2% topical glycopyrrolate on one half of the forehead while the other half of the forehead was treated with a placebo.

RESULTS: The sweat production rate of the half of the forehead treated with topical glycopyrrolate was significantly reduced to 37.6 +/- 2.8 mg min^-1 (mean +/- SEM) compared with 102.2 +/- 5.5 mg min^-1 at the placebo-treated half of the forehead (P<0.001). Patients evaluated their degree of anhidrosis as excellent in six (24%) patients, good in 16 (64%), fair in two (8%) and poor in one (4%). Twenty-four patients (96%) were partially or fully satisfied with their fair to excellent anhidrosis; only one patient (who developed a transient headache after treatment) was dissatisfied with its therapeutic effect. Only seven patients (28%) experienced recurrence within 1 day while 17 patients (68%) had recurrence within 2 days. One patient (4%) remained stable for up to 4 days.

CONCLUSIONS: Topical glycopyrrolate application appears to be effective and safe for the treatment of excessive facial sweating in primary craniofacial and secondary gustatory hyperhidrosis following sympathectomy. PMID: 18294315

With our state of the art compounding lab and pharmaceutical experience, we have the ability to compound glycopyrrolate into a topical cream, lotion or antiperspirant stick.

An example of how you might prescribe follows:

**COMPOUNDED MEDICATION**

<table>
<thead>
<tr>
<th>Glycopyrrolate 1%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topical Cream</strong></td>
</tr>
<tr>
<td>30gm</td>
</tr>
<tr>
<td>Apply sparingly to dried, affected area(s) QD</td>
</tr>
</tbody>
</table>
**CUTANEOUS CANDIDIASIS**

The following clinical paper discusses the practicability of using ibuprofen, alone or in combination with azoles, in the treatment of cutaneous candidiasis, particularly when applied topically, taking advantage of the drug's antifungal and anti-inflammatory properties - “Antifungal activity of ibuprofen alone and in combination with fluconazole against Candida species” *(J Med Microbiol. 2000 Sep;49 (9):831-40)*.

**OBJECTIVE:** “Ibuprofen, a non-steroidal anti-inflammatory drug, exhibited antimicrobial activity against Candida albicans and non-albicans strains. At 10 mg/ml, ibuprofen showed a rapidcidal activity against exponential growth phase C. albicans, accompanied by rapid and extensive leakage of intracellular K+, permeation to propidium iodide, lysis of spheroplasts and severe membrane ultrastructural alterations. These results indicate that the killing of Candida cells is due to direct damage to the cytoplasmic membrane. At 5 mg/ml, ibuprofen inhibited growth; however, it did not kill the yeasts and did not directly affect the cytoplasmic membrane. Evaluation of yeast metabolic vitality with the fluorescent probe FUN-1 showed that growth inhibition induced by the fungistatic drug concentration was due to metabolic alterations. The combination of ibuprofen with fluconazole resulted in synergic activity with eight of the 12 Candida strains studied, including four of the five fluconazole-resistant strains. The MICs of fluconazole for the fluconazole-resistant strains decreased 2-128-fold when the drug was associated with ibuprofen. When in combination with fluconazole, MICs for ibuprofen decreased by up to 64-fold for all the 12 strains studied. These results point to the practicability of using ibuprofen, alone or in combination with azoles, in the treatment of candidosis, particularly when applied topically, taking advantage of the drug's antifungal and anti-inflammatory properties.” PMID: 10966233

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**COMPOUNDED MEDICATION**

Ibuprofen 10%/Fluconazole 1%
Topical Cream
60gm
Apply to affected area(s) BID

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound ibuprofen and fluconazole together as one topical cream.

An example of how you might prescribe follows:
LOW BACK PAIN

The following study finds that diclofenac is an effective and safe treatment of acute low back pain -“Relief of acute low back pain with diclofenac-K 12.5 mg tablets: a flexible dose, ibuprofen 200 mg and placebo-controlled clinical trial” (Int J Clin Pharmacol Ther. 2003 Sep;41(9):375-85).

OBJECTIVE: To assess efficacy and safety of diclofenac-K 12.5 mg tablets in the treatment of acute low back pain (low back pain).

MATERIAL METHOD: A multiple dose, double-blind, double-dummy, randomized, placebo-controlled, parallel group trial compared diclofenac-K (12.5 mg; n = 124) with ibuprofen (200 mg; n = 122) and placebo (n = 126) in patients with moderate-to-severe acute low back pain. Safety/tolerability was assessed by recording adverse events.

RESULTS: Diclofenac-K 12.5 mg demonstrated superiority vs. placebo on the primary efficacy parameter and almost all secondary initial dose outcomes. With respect to the initial dose, diclofenac-K 12.5 mg was also significantly superior to ibuprofen 200 mg on SPID-3. Ibuprofen 200 mg was superior to placebo only on the End of First Dose global efficacy assessment. The flexible multiple dosing regimens of diclofenac-K and ibuprofen were both significantly superior to placebo on the End of Study global efficacy assessment, time to rescue medication over the entire study period, the End of Day global efficacy assessment on Days 1-2, pain intensity difference on the VAS at Visit 3 and the Eifel algofunctional index at Visit 3 (also at Visit 2 in diclofenac-K 12.5 mg group). Both active treatments were as well tolerated as placebo.

CONCLUSIONS: The flexible multiple dosing regimen of diclofenac-K 12.5 mg (initial dose of 2 tablets followed by 1-2 tablets every 4-6 hours, max. 75 mg/day) is an effective and safe treatment of acute low back pain. PMID: 14518597

This study concludes that cyclobenzaprine was effective in treating muscle spasm associated with painful musculoskeletal conditions -“Cyclobenzaprine ER for muscle spasm associated with low back and neck pain: two randomized, double-blind, placebo-controlled studies of identical design” (Curr Med Res Opin. 2009 May;25(5):1179-96).

OBJECTIVE: To evaluate efficacy and tolerability of once-daily cyclobenzaprine extended release (CER) 15- and 30-mg capsules in patients with muscle spasm associated with acute, painful musculoskeletal conditions.

METHODS: Two identically designed, randomized, double-blind, placebo- and active-controlled, parallel-group studies in patients aged 18-75 years with muscle spasm associated with neck or back pain.

RESULTS: A total of 156/254 randomized patients in study 1 and 174/250 in study 2 completed 14 days of treatment. Significant improvements in patient’s rating of medication helpfulness were reported with CER versus placebo (CER 30 mg, study 1, p = 0.007; CER 15 mg, study 2, p = 0.018) at day 4. Significant improvements with CER 30 mg versus placebo were also seen at day 4 in study 1 for patient-rated global impression of change (p = 0.008), relief of local pain (p = 0.004), and restriction of movement (p = 0.002). Neither study reported differences between study groups on the physician’s clinical global assessment. Improvements with CER were comparable to that of CIR. In both studies, daytime drowsiness was reported more frequently in active treatment groups than in the placebo group; however, reports of drowsiness decreased over time in all groups. In general, daytime drowsiness was reported more frequently in CIR groups than in CER groups. More adverse events were reported in the active treatment groups versus placebo and were similar in the CER and CIR groups, except somnolence, which occurred more frequently with CER.

CONCLUSIONS: : Once-daily CER 15 mg (study 2) and CER 30 mg (study 1) were effective in treating muscle spasm associated with painful musculoskeletal conditions after 4 days of treatment. Differences between CER and placebo groups did not reach statistical significance on all efficacy measures, and the protocols were not powered to detect differences between active treatment arms. CER was generally safe and well tolerated, with low rates of somnolence. PMID: 1932361

An example of how you might prescribe follows:

**COMPOUNDED MEDICATION**

**Diclofenac 5% / Cyclobenzaprine 1% Transdermal Cream**

120 gm

Apply locally TID-QID

We have the ability to compound diclofenac and cyclobenzaprine into one transdermal cream. This combination cream allows for a more flexible dosing, and may result in greater efficacy and/or fewer systemic side effects than either drug dosed orally.
Hyperhidrosis

[ ] Glycopyrrolate 1% Topical Cream
Quantity 30gm Directions: Apply sparingly to dried, affected area(s) QD

Cutaneous Candidiasis

[ ] Ibuprofen 10%/Fluconazole 1% Topical Cream
Quantity 60gm Directions: Apply to affected area(s) BID

Low Back Pain

[ ] Diclofenac 5%/Cyclobenrazprine 1% Transdermal Cream
Quantity 120gm Directions: Apply locally TID-QID

Directions

____________________________________________________

Prescriber’s Signature___________________________________ Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

All topical compound %s are per 1 ml or 1 gm unless otherwise noted

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