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for the specific needs of our patients.*

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PRESCRIPTION COMPOUNDING FOR

**OBSTETRICS &
GYNECOLOGY**

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VULVODYNIA

The following study found that topical gabapentin seems to be well-tolerated and associated with significant pain relief in women with vulvodynia - "Topical gabapentin in the treatment of localized and generalized vulvodynia" (*Obstet Gynecol.* 2008 Sep;112(3):579-85).

ABSTRACT

OBJECTIVE: To evaluate the clinical efficacy and tolerability of topical gabapentin in the treatment of women with vulvodynia.

METHODS: A retrospective study was designed to ascertain clinical responses to topical gabapentin. Patient demographic and medical characteristics, including present and prior treatment for vulvodynia, were routinely collected. The final outcome was defined by a comparison between pretreatment and posttreatment mean pain scores based on a discrete visual analog scale of 0 to 10. Categorical data were compared by Fisher exact test, continuous variables between groups by the Wilcoxon rank sum test, and mean change in pain score between pretreatment and posttreatment by paired Student t test.

RESULTS: Between January 2001 and December 2006, 51 women with vulvodynia (19 or 37% with generalized vulvodynia, 32 or 63% with localized) were treated with 2% to 6% gabapentin. After a minimum of 8 weeks of therapy, the mean pain score among the 35 evaluable women was significantly reduced from 7.26 to 2.49 (mean change -4.77, 95% confidence interval -5.47 to -4.07). Overall, 28 of 35 (80%) demonstrated at least a 50% improvement in pain scores. Among patients with localized vulvodynia, sexual function improved in 17 of 20 with evaluable results (6 of 9 reinstated vaginal intercourse, whereas all 11 patients experiencing decreased frequency of intercourse reported increased frequency after treatment). Discontinuations occurred in 7 of 50 (14%) treated.

CONCLUSION: Topical gabapentin seems to be well-tolerated and associated with significant pain relief in women with vulvodynia.

LEVEL OF EVIDENCE: III. PMID: 18757655

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

Gabapentin 6%
Vaginal Cream
 60gm
 Apply sparingly BID

This study found that gabapentin appears to be very effective in the treatment of generalized vulvodynia, unprovoked - "Evaluation of gabapentin in the treatment of generalized vulvodynia, unprovoked" (*J Reprod Med.* 2007 Feb;52(2):103-6).

ABSTRACT

OBJECTIVE: To determine the efficacy of gabapentin in the treatment of generalized vulvodynia, unprovoked, to determine the most common presenting symptoms in patients with this diagnosis, to evaluate the prevalence of comorbidities in these patients and to determine the possibility of comorbidities or specific presenting symptoms that decrease the efficacy of this drug.

STUDY DESIGN: The charts of all women seen in our facility with a diagnosis of generalized vulvodynia between January 1, 2002, and September 30, 2004, were reviewed. A total of 601 charts were reviewed. Patients were included in the study if they had a diagnosis of generalized vulvodynia, they were treated with single-agent gabapentin, had follow-up for 30 months or more and had adequately documented follow-up.

RESULTS: A total of 152 patients were included in the study. Ninety-eight (64%) patients treated with gabapentin had resolution of at least 80% of their symptoms during the study period. Forty-nine (32%) did not have adequate resolution. There was a high percentage of comorbidities in patients with generalized vulvodynia. Sleep disturbance was the only comorbidity that negatively affected the efficacy of gabapentin. In addition, there appeared to be a trend toward a less favorable response in patients with a longer period of untreated illness (p value not less than 0.05). Side effects of gabapentin were few. Forty (26%) reported some side effects. Fatigue was the most common complaint. Seventeen patients (11%) discontinued the medication secondary to side effects.

CONCLUSIONS: Gabapentin appears to be very effective in the treatment of generalized vulvodynia, unprovoked. It has a very low side effect profile. Certain patients may be less likely to benefit from gabapentin, including those with the comorbidity of sleep disturbance. Patients with symptoms of longer-standing generalized vulvodynia, unprovoked, may also be less likely to benefit from this treatment. PMID: 17393770

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound gabapentin as a vaginal cream; in strengths that meet the unique needs of each of your patients.

VULVOVAGINAL CANDIDIASIS

The following clinical paper reviews the mechanism of antifungal activity for boric acid - "Antifungal mechanisms supporting boric acid therapy of *Candida vaginitis*" (*J Antimicrob Chemother.* 2009 Feb;63(2):325-36).

ABSTRACT

BACKGROUND: Boric acid is a commonly cited treatment for recurrent and resistant yeast vaginitis, but data about the extent and mechanism of its antifungal activity are lacking.

OBJECTIVES: The aim of this study was to use in vitro methods to understand the spectrum and mechanism of boric acid as a potential treatment for vaginal infection.

METHODS: Yeast and bacterial isolates were tested by agar dilution to determine the intrinsic antimicrobial activity of boric acid. Established microbial physiology methods illuminated the mechanism of the action of boric acid against *Candida albicans*.

RESULTS: *C. albicans* strains (including fluconazole-resistant strains) were inhibited at concentrations attainable intravaginally; as were bacteria. Broth dilution MICs were between 1563 and 6250 mg/L and boric acid proved fungistatic (also reflected by a decrease in CO₂ generation); prolonged culture at 50,000 mg/L was fungicidal. Several organic acids in yeast nitrogen broth yielded a lower pH than equimolar boric acid and sodium borate but were less inhibitory. Cold or anaerobic incubation protected yeast at high boric acid concentrations. Cells maintained integrity for 6 h in boric acid at 37 degrees C, but after 24 h modest intrusion of propidium iodide occurred; loss of plate count viability preceded uptake of vital stain. Growth at sub-MIC concentrations of boric acid decreased cellular ergosterol. The drug efflux pump CDR1 did not protect *Candida* as CDR1 expression was abrogated by boric acid. Boric acid interfered with the development of biofilm and hyphal transformation.

CONCLUSIONS: Boric acid is fungistatic to fungicidal depending on concentration and temperature. Inhibition of oxidative metabolism appears to be a key antifungal mechanism, but inhibition of virulence probably contributes to therapeutic efficacy in vivo.
PMID: 19059942

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

**Boric Acid 600mg
Vaginal Suppository
#15
Insert 1 suppository QD**

This clinical study supports the use of boric acid in the management of VVC -"Prolonged (3-month) mycological cure rate after boric acid suppositories in diabetic women with vulvovaginal candidiasis" (*J Infect.* 2007 Oct;55(4):374-7).

ABSTRACT

OBJECTIVE: Patients with diabetes mellitus (DM) are at increased risk of vulvovaginal candidiasis (VVC) due to *C. glabrata*. In our previous study we had shown that patients with diabetes mellitus and VVC show an overall superior mycological cure rate (74% versus 51%) with boric acid therapy at 15th day as compared to fluconazole. Present study was carried out to assess long term response to boric acid in diabetic women with VVC.

MATERIAL & METHODS: Subjects included 40 consecutive diabetic women (type 2 DM=26 and type 1 DM=14) who had achieved mycological cure (high vaginal swab culture negativity) on day 15 of therapy following single-dose oral-150 mg fluconazole (n=21) or 600 mg of boric acid suppositories given daily for 14 days (n=19). At third month of follow up, patients were assessed for signs and symptoms of VVC and a repeat HVS was collected for fungal culture. HbA1c was measured to assess glycaemic control.

RESULTS: The mean age, BMI, HbA1c and frequency of various *Candida* species isolated at initial diagnosis were comparable in the fluconazole and boric acid treatment groups. Fifteen of 21 (71.4%) and 12 of 19 (63.1%) women who achieved mycological cure at 15 day remain cured at three months in the fluconazole and boric acid treated groups, respectively (P=0.83). With 74% mycological cure at 15th day, this would indicate that on an average only 46.6% of diabetic women with VVC would remain cured at 3 months after a course of 14 days boric acid therapy. Most of the patients relapsed with no change in *Candida* species. The demographic profile and mean HbA1c (8.6+/-2.2 versus 8.8+/-2.4%, P=0.83) were comparable in patients with (n=27) and without mycological cure (n=13).

CONCLUSIONS: The results of the current study indicating comparable mycological cure rate at 3 months between fluconazole and boric acid treated patients would support use of boric acid in the acute management of VVC in view of its superior short term response in diabetic women with *C. glabrata* infections. However, there is need to explore other therapeutic regimens which are effective in achieving long term mycological cure in diabetic women with VVC. PMID: 17692922

We have the ability to compound boric acid into vaginal suppositories at various strengths to meet the unique needs of each of your patients.

BREASTFEEDING CHALLENGES

This formula is utilized for all types of nipple soreness including candida, and is advocated for by Dr. Jack Newman, founder of the Newman Breastfeeding Clinic & Institute (NBCI). The following is an excerpt from their website www.drjacknewman.com.

ABSTRACT: “The Newman Breastfeeding Clinic & Institute (NBCI) is staffed by a multi-disciplinary team of healthcare professionals including International Board Certified Lactation Consultants, Physicians, Nurses, La Leche League, Doulas, and visiting Naturopaths. NBCI offers support and treatment for mothers experiencing breastfeeding challenges and presents prenatal breastfeeding classes for expectant families. We provide consistent and evidence-based information that empowers mothers to successfully reach their own breastfeeding goals.

“APNO starts with Mupirocin 2%, Betamethasone 0.1%, to which is added miconazole powder so that the final concentration is 2% miconazole. This combination gives a total volume of just more than 30 grams. Clotrimazole powder to a final concentration of 2% may be substituted if miconazole powder is unavailable, but both exist (the pharmacist may have to order it in, but compounding pharmacies almost always have it on hand). I believe clotrimazole is not as good as miconazole. Using powder gives a better concentration of antifungal agent (miconazole or clotrimazole) and the concentrations of the mupirocin and betamethasone remain higher. Sometimes

we will add ibuprofen powder to a final concentration of 2%. The combination is applied sparingly after each feeding (except the feeding when the mother uses gentian violet). “Sparingly” means that the nipple and areola will shine but you won’t be able to see the ointment. Do not wash or wipe it off, even if the pharmacist asks you to. I used to use nystatin ointment or miconazole cream (15 grams) as part of the mixture, and these work well enough, but I believe the use of powdered miconazole (or even clotrimazole powder) gives better results. These ointments can be used for any cause of nipple soreness (“all purpose nipple ointments”), not just for Candida (yeast). Use the ointment until you are pain free and then decrease frequency over a week or two until stopped. (See Handout #3b Treatments for Sore Nipples and Sore Breasts under “all purpose nipple ointment”). If you are not having less pain after 3 or 4 days of use, or if you need to be using it for longer than two or three weeks to keep pain free, get help or advice.”



With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound mupirocin, betamethasone, and miconazole together as a topical ointment.

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

Mupirocin 2% / Betamethasone 0.1% / Miconazole 2%

Topical Ointment

30gm

Apply sparingly to nipples after each feeding

Prescriber Name _____

Prescriber Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

Date _____ Patient Name _____ DOB _____

Address _____ City/State/Zip _____ Phone _____

Patient will pick up at pharmacy Please ship to patient

Bill Insurance Plan: _____ ID# _____

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

Vulvodinia

[] Gabapentin 6%

Vaginal Cream

Quantity 60gm

Directions: Apply sparingly BID

Vulvovaginal Candidiasis

[] Boric Acid 600mg

Vaginal Suppository

Quantity #15

Directions: Insert 1 suppository QD

Breastfeeding Challenges

[] Mupirocin 2%/Betamethasone 0.1%/Miconazole 2%

Topical Ointment

Quantity 30gm

Directions: Apply sparingly to nipples after each feeding

Directions

Prescriber's Signature _____ Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

