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PRESCRIPTION COMPOUNDING FOR

OBSTETRICS & GYNECOLOGY

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ATROPHIC VAGINITIS

The following clinical study finds that intravaginal administration of a combination of estriol and progesterone agent to women with atrophic vaginitis may represent a safe and effective alternative to systemic hormone replacement - “Efficacy and safety of vaginal estriol and progesterone in postmenopausal women with atrophic vaginitis” (Menopause, 2009 Apr 22).

OBJECTIVE: The aim of this study was to assess the efficacy and safety of intravaginal estriol and progesterone on atrophic vaginitis in postmenopausal women.

METHODS: Under a physician-sponsored Investigational New Drug application, 19 healthy postmenopausal women with atrophic vaginitis received vaginal suppositories containing estriol (1 mg) and progesterone (30 mg). The participants were instructed to insert one suppository intravaginally once daily for 2 weeks and thrice weekly for a total of 6 months. Vaginal pH, Vaginal Maturation Index, urinalysis, self-reported vaginal dryness, menopausal quality of life, and serum estriol and progesterone levels were measured at enrollment and after 3 and 6 months of suppository use. Endometrial biopsies were obtained at enrollment and at 6 months. After 2 weeks of therapy, 6 participants had serum estriol and progesterone measured.

RESULTS: The Vaginal Maturation Index, vaginal pH, and vaginal dryness rating improved significantly at 3 and 6 months compared with baseline. Menopausal quality of life scores improved significantly in all domains, with the sexual subscale showing the most improvement. There were no cases of endometrial hyperplasia after 6 months of suppository use. Serum preinsertion estriol at week 2 and months 3 and 6 were similar to baseline levels. Serum preinsertion progesterone increased but returned to baseline preinsertion levels at month 6, and preinsertion levels were significantly less at month 6 compared with month 3.

CONCLUSIONS: Intravaginal administration of a combination estriol and progesterone agent to women with atrophic vaginitis may represent a safe and effective alternative to systemic hormone replacement, although this study was not adequate to provide proof of efficacy given that it was uncontrolled. PMID: 19390463

We have the ability to compound estriol and progesterone together in several unique forms of delivery.

An example of how you might prescribe follows:

<table>
<thead>
<tr>
<th>COMPOUNDED MEDICATION</th>
</tr>
</thead>
</table>

**Estriol 1mg / Progesterone 30mg**  
**Vaginal Suppository**  
#30  
Insert one suppository QD for 2 weeks, then 3x per week for 6 months
NAUSEA/VOMITING DURING PREGNANCY

The following review concludes that meclizine can be used safely for nausea and vomiting in pregnancy -"Delivery outcome after the use of meclizine (sic) in early pregnancy" (Eur J Epidemiol. 2003;18(7):665-9).

**ABSTRACT:** “In some countries, including Sweden, no risk is considered to exist with the use of meclizine for nausea and vomiting in pregnancy (NVP), but in other countries warnings against use during pregnancy are given. Rat tests indicate a teratogenic risk and published epidemiological studies are of restricted size. Delivery outcome was studied in 16,536 women who reported the use of meclizine in early pregnancy and was compared with all 540,660 women who gave birth. Information on drug usage was obtained prospectively in early pregnancy. Risk factors for using meclizine were young maternal age, to have had a previous child, not to smoke, to have a low body mass index. The use of some other drugs (antihypertensives, thyroxine, anticonvulsants) decreased the use of meclizine. Maternal diagnoses of preeclampsia or diabetes were less frequent when the woman had used meclizine. The twinning rate was increased and the sex distribution of the infants low (female excess). Preterm birth, low birth weight, short body length, and small head circumference occurred at a reduced rate after meclizine use, notably for boys. Also the rate of congenital malformations was reduced. If anything, delivery outcome is better than expected when the mother used meclizine. These beneficial effects are probably secondary to NVP. Meclizine can apparently be used without risk at this condition.” PMID: 12952140

Meclizine was evaluated in three large prospective studies to assess for teratogenicity. In all three studies, meclizine therapy was compared with no drug therapy during pregnancy; rates of malformations in the drug therapy and no drug therapy groups were not statistically different. In a large collaborative perinatal project, diphenhydramine (595 women) and dimenhydrinate (319 women) administered during the first trimester of pregnancy was not associated with major or minor malformations. In addition, two reports concerning antihistamines prescribed during pregnancy to treat asthma and allergic symptoms found that diphenhydramine and dimenhydrinate carried a low teratogenic risk.” PMID:16945050

**COMPOUNDED MEDICATION**

**Meclizine 2.5% Transdermal Cream**

30gm

Apply 1gm to inner wrist Q4-6H PRN

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound meclizine into a transdermal cream that can be applied directly to the wrist. This form of delivery may be preferable for some patients.
CERVICAL DYSPLASIA

The results of the following study suggest that intravaginal DHEA is safe and well tolerated, and may promote regression of low-grade cervical lesions -“Long-term administration of intravaginal dehydroepiandrosterone on regression of low-grade cervical dysplasia—a pilot study” (Gynecol Obstet Invest. 2003;55(1):25-31).

**ABSTRACT:** “Although many dysplastic cervical lesions regress spontaneously, treatment is common due to concern for progression. Lesions persist or progress in women whose immune systems are unable to clear infection by human papillomavirus (HPV). Dehydroepiandrosterone (DHEA) is an adrenal steroid that has both immune modulatory and tumor inhibitory activity. A pilot study was conducted to examine the feasibility, safety and potential efficacy of intravaginal DHEA in women with low-grade cervical dysplasia. Twelve women with low-grade dysplasia, confirmed by colposcopic exam, were given 150 mg of intravaginal micronized DHEA daily for up to 6 months. Follow-up evaluations of the cervix were done at 3 and 6 months of use.

DHEA, DHEA-S, androstenedione and testosterone levels were also measured. By the end of the study period, 10 of the 12 women (83%) had no evidence of dysplasia; the remaining 2 had normal colposcopic exams but cytology showing atypical cells of undetermined significance. There were no serious side effects. Androstenedione levels were elevated at 3 months, whereas testosterone levels were unchanged over the course of treatment. The results suggest that intravaginal DHEA is safe and well tolerated and may promote regression of low-grade cervical lesions. Further study is needed to establish efficacy.” PMID: 12624548

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound DHEA into a vaginal cream.

An example of how you might prescribe follows:

**COMPOUNDED MEDICATION**

<table>
<thead>
<tr>
<th>DHEA 15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal Cream</td>
</tr>
<tr>
<td>30gm</td>
</tr>
<tr>
<td>Apply 1gm intravaginally QHS</td>
</tr>
</tbody>
</table>
All topical compounds are per 1 ml or 1 gm unless otherwise noted

**Atrophic Vaginitis**
- [ ] Estriol 1mg / Progesterone 30mg  Vaginal Suppository
  - Quantity #30
  - Directions: Insert one suppository QD for 2 weeks, then 3x per week for 6 months

**Nausea/Vomiting during Pregnancy**
- [ ] Meclizine 2.5%  Transdermal Cream
  - Quantity 30gm
  - Directions: Apply 1gm to inner wrist Q4-6H PRN

**Cervical Dysplasia**
- [ ] DHEA 15%  Vaginal Cream
  - Quantity 30gm
  - Directions: Apply 1gm intravaginally QHS

**Directions**

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