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CONCIERGE PERSONALIZED CARE
GYNECOLOGY • HORMONE THERAPY
INTEGRATIVE MEDICINE

Alternative Estrogen and Progesterone Products, [including Bioidentical and Naturopathic Formulations]

Vulva-Vaginal Atrophy – Treatment Options:

- Vagifem – 10 mg. tab inserted vaginally
- Vaginal Estrogen Cream – Premarin, Estrace
- Estring – vaginal estradiol (2 mg) – replace every 3 months
- DHEA Ovules – Pasterone (**Intrarosa**) – converts to intra-cellular estradiol
- SERM - Ospemifene (Osphena) – 60 mg oral tab
- Lubricants: Replens, Sylk

Pharmaceutical (Prescription) Estradiol (E2) Options:

- Oral: Premarin (conjugated estrogen), Estrace (Estradiol),
- Trans-Dermal Patch: Alora, Climara, Estraderm, Estradiol Patch, Vivelle, Vivelle-Dot
- Gel: Estragel pump
- Spray mist: Evamist spray
- Trans-Vaginal Ring: FemRing (0.05 & 0.1 mg), q 90 days
- Injectable:
 - Pellet: sub-Q insertion, local anesthesia, lasts 3-5 months
 - Depo-Estradiol lasts 3-4 weeks

Initial Dosage of Estrogen

- Low dose transdermal estradiol (0.5 mg) is used initially
- Symptom improvement with 'List' highlighted - reviewed after 1 month
- Dosage is slowly adjusted higher until identified vasomotor symptoms are 100% controlled
- Brand vs Generic – is usually a matter of \$\$\$
- Continuous vs Cyclical dosing with progesterone – depends on if a woman is still menstruating

Progesterone (Required, if the uterus is present or the patient has history of endometriosis)

- Oral, Trans-dermal, Trans-vaginal gel or suppository, IUD (Mirena, Liletta, Skyla)
- Continuous vs cyclical dosing with estrogen
- Brand vs Generic vs Compounded
- Dosage: Increased as level of estrogen dose is increased

SERM's – Selective Estrogen Receptor Modulator

- Agonist (positive) vs Antagonist (negative) effects on estrogen receptors at cellular level of all the body organs and tissues.
- Bazedoxifene (DuaVee) – contains conjugated estrogen. FDA for HRT with intact uterus
- Tamoxifen – FDA approved for breast cancer
- Raloxifene (Evista) – FDA approved for osteoporosis

Testosterone:

- FDA approved for men, NOT for women
- Compounded testosterone available in men and women

Medications:

- **Anti-Depressants:**
 - SSRI: paroxetine (Paxil)
 - SNRI: venlafaxine (Effexor)
- **Gabapentin**
- **Clonidine** (Catapres)

List of Naturopathic Supplements (may help with the milder menopause symptoms):

- **Isoflavones:**
 - Phytoestrogens (Soy) (e.g. Estroven) - hot flashes, night sweats, vaginal dryness
 - Red Clover - hot flashes, night sweats
- **Black Cohosh** - hot flashes, night sweats
- **St. John's Wort** - mild depression
- **Green tea**
- **Dong quai** – herbal remedy for hot flashes

Alternative Therapies for Menopausal (Vasomotor and Emotional) Symptoms

For many women concerns about taking estrogen prompt them to rely on 'natural' alternative medicines to improve or control their symptoms. Estradiol is the primary estrogen produced during the reproductive-aged women. **Phytoestrogens** are naturally occurring in plant substrates and are functionally like a weak form of estradiol. It is important to recognize that all steroid hormones are derived from three major plant sources: soybeans, Chinese cactus needles and Mexican yams, except for conjugated estrogens (Premarin). Therefore, these products are all natural. The issue with over-the-counter remedies is the absence of any quality or potency control. These 'natural' products are completely unregulated regarding their safety. Further, there are no reliable studies that have demonstrated that these alleged remedies for mild symptoms are giving any protection for the tissues and disease prevention.

Role of Compounding Pharmacies for HRT Therapy

The WHI study used an oral estrogen (Premarin), which has now been proven to be safe and protective. The progesterone (Provera) the study used was synthetic (not bio-identical) and was associated with a small increase in breast cancer risk. Bio-identical estrogen and bio-identical progesterone have a molecular structure that is *identical* to those produced by the ovary and has the same action at the receptor sites of the body's tissues. It is important to note that in this day of generic pharmaceutical drugs (obtained at local or web pharmacies) the purity and actual amount of a hormone may not always be what the label states, even though it is 'FDA approved'. There is a lack of regulation of FDA-approved bio-identical hormones prepared by compounding pharmacists. Currently, there are about 8000 pharmacies in the U.S. that compound medications. All 50 states have a Board of Pharmacy that licenses pharmacies within its State. While any pharmacy may compound non-sterile preparations of drugs the standards vary greatly and are generally unregulated. If a patient is going to use a compounding pharmacy for her medication, then I would recommend selecting a pharmacy accredited by the Pharmacy Compounding Accreditation Board (PCAB). The PCAB currently accredits about 200 pharmacies in the U.S. for quality assurance standards that ensure that medications (tablets, capsules, gels and creams) contain exactly what the label states. Web link: www.pcab.org/consumers.

In Summary:

- Compounding pharmacies are Not FDA regulated
- State Pharmacy Boards license and regulate pharmacies
- Licensing is required for sterile (injectable) products vs non-sterile (topical or oral) products

- Accreditation is Voluntary:
- United Credentialing and Accreditation Program (UCAP) is administered by the National Association of Boards of Pharmacy – NABP
- Accreditation Commission for HealthCare (ACHC)
 - Allows for individualization in hormones used and dosage variability
 - Usually not covered by medical insurance companies
 - Formulations:
 - Estrogen: Estradiol (20%) + Estriol (80%); cream or gel – referred to as ‘Bi-Est’
 - Progesterone:
 - Oral: Micronized progesterone (Prometrium) passes via liver and metabolized to 4-allopregnanolone, a positive modulator at GABA receptor, which produces a sedative effect.
 - Trans-dermal: Not metabolized to 4-allopregnanolone and to benefit on sleep
 - Pregnenolone:
 - A neuro-steroid and is metabolized to progesterone.
 - Pregnenolone (25 mg) usually combined with DHEA (5-10 mg); oral admin.
 - Used as mood stabilizer and improve sleep and immune system; ? effect on anti-aging
 - Testosterone:
 - Women: Dosage – 1, 2, 4 mg; gel or cream
 - Indicated with a low total and free testosterone
 - DHEA:
 - Metabolizes to estradiol and testosterone
 - Role in anti-aging and immunity
 - Dosage: 5, 10, 25 mg. (higher doses may cause acne)

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