

Georgia Hormones, P.C.

Robert P. Goldman, MD

3400-A Old Milton Pkwy, Suite 360, Alpharetta GA 30005 770-475-0077

www.GeorgiaHormones.com

02-18-2006

COMMERCIAL, NON-COMPOUNDED BIOIDENTICAL HORMONES

Skin Patches:

Commercial skin patches are an effective and reliable mode of steroid hormone administration. They are more reliable than topical creams and gels. Because they sit on the skin continuously, they give an even flow of hormone on a steady basis. Because the patent is on the patch, rather than the hormone inside, bioidentical hormone can be used and the manufacturer can still have a patent on their product. Only hormones used in tiny doses can be given by skin patch. **There are several bioidentical Estradiol patches.** Although they could be made, no manufacturer has yet gotten approval for a female Testosterone patch. Progesterone is given in doses twenty to one hundred times that of Estradiol. **There will probably never be a bioidentical Progesterone patch.** The combination patches use oral contraceptive synthetic progestins not real Progesterone.

Advantages:

The Estradiol patches give a very steady output of hormones. Estrogen is not used up as it stimulates protein manufacture in the nucleus of target cells. Under normal circumstances, estrogens are made intermittently. Capsules, tablets and creams are used only once or twice a day. Blood levels rise after administration, and then fall. Constant exposure has a much more powerful effect than intermittent exposure. **Therefore, it takes only a very small amount in a patch to be effective.** I first began using patches in women who were rapid metabolizers of Estradiol. They would run out of hormone by the end of the day. Initially, looking at the small daily output of the patch, I used the strongest ones. I found that many patients exhibited signs of estrogen excess. I have gradually used mostly the lower dose patches. **Even though the serum Estradiol levels are not that high, the physiologic effect is great.**

Disadvantages:

They only work if they stay on. Avid swimmers, hot tub users and women who perspire a great deal may not be able to keep them on. Some women are allergic to the glue that holds them on. I initially thought a once a week patch would be more convenient than a twice a week change. I have found, though, that many more women are irritated by the once a week Climara than the twice-weekly Vivelle Dot. The serum levels seem to be about the same. I now use Vivelle Dot almost exclusively.

Available choices:

- Alora, estradiol transdermal, 0.025, 0.05, 0.075, 0.01 (0.0375 is now my #1 choice, not available)
- Generic estradiol patch, 0.05, 0.1, very large, irritating, adheres poorly, **not recommended**
- Climara 0.025, 0.0375, 0.05, 0.06, 0.075, 0.1 weekly change, more irritating, looks dirty by day 5 or 6
- Climara Pro estradiol/levonorgestrel, 0.045/0.015 weekly change, non-bioidentical progestin
- Combipatch estradiol/norethindrone acetate 0.05/0.14, 0.05/0.25 twice weekly, non-bioidentical progestin
- Estraderm 0.05, 0.1 twice weekly
- Menostar 0.014/day estradiol, one strength only, **lowest available dose**, weekly change
- Vivelle-Dot (mg/day) 0.025, 0.0375, 0.05, 0.075, 0.1 twice weekly
- Vivelle same doses, larger, not as well tolerated, twice weekly

Vaginal Rings:

There are three choices of vaginal rings.

The Estring is a very low dose ring used for vaginal atrophy. It is good choice for the elderly and it also adds some pessary like support. If the uterus is in place, a small amount of progesterone cream may add protection from endometrial cancer, but the risk is low.

Femring is an entirely different product. It is a high dose HRT; probably too high a dose for many women. Full progesterone replacement will also be needed as with any Estradiol replacement.

Advantages:

It is easy therapy. Once placed you have ninety days continuous therapy.

Disadvantages:

The Estring is not full HRT. I use it only in the elderly. If the patient has no drug plan, it is almost ninety dollars. It costs dollar a day for the ring.

Femring is equivalent to the highest doses of the patch. The 0.1 is probably only useful in a young woman after surgical sterilization. I have seen heavy yeast infections from the Femring. Progesterone balance is needed with a uterus or not.

Available choices:

- Estring, estradiol 2mg released over 90 days. Very low dose for atrophy only.
- Femring, estradiol 0.05, 0.1 mg/day released over 90 days. Full dose HRT, add Progesterone

Vaginal Tablets:

- **Vagifem** is the only product in this category. Each tablet is 0.025 mg of Estradiol. If used daily, it would be equivalent to the lowest dose patches. Even a few times a week, there would be some risk of endometrial cancer if no progesterone or a progestin were given. They are eighteen to a pack and expensive. They help vaginal atrophy because the hormone is concentrated where it is needed. A **vaginal cream of equivalent dosage made by a compounding pharmacist would probably be much less expensive.** In the elderly, medications may not be paid by insurance.

Vaginal Creams:

The advantages of vaginal creams are described in the Compounding Pharmacy section. Estrace works out to one mg/ml of cream. Depending on the absorption in the individual patient, one half to one ml/day would probably give adequate HRT. Again, these are therapeutic levels and Progesterone will be needed. The price of Estrace has really risen in the last few years. **The compounded equivalent would probably be cheaper.**

- Estrace Vaginal, estradiol in vaginal cream, 0.01%
- Premarin Vaginal Cream, 0.625mg/ml, non-bioidentical. Full HRT, not measurable.

Pump Dispensers of Topical Creams:

There are now several commercial gels and creams. One would have to get blood levels on a group of patients to see what kinds of levels are achieved. It should be bioidentical. This is full HRT. The issues of hormone balance still hold. Commercial topical products could be used instead of compounded products. The actual cost and relative costs including insurance issues may make the decision. If purchased in quantity, when you consider multiple co-pays, the compounded creams and gels might be less expensive.

- EstroGel estradiol topical gel, 0.06%, each pump is 1.25g of gel.

Oral Tablets:

There are many branded and generic Estradiol tablets. They are usually in only three doses: 0.5mg, 1 mg and 2 mg. For menopausal women, these are high doses. Tablets could be split with a pill cutter if necessary. All the issues of oral versus non-oral routes come into play. These are bio-identical hormone products.

Prometrium:

Prometrium is bioidentical, micronized progesterone mixed with peanut oil. The purpose of the peanut oil formula is mostly to acquire a patent.

Advantages:

It is available in all pharmacies and is covered by most insurance.

Disadvantages:

Many women feel faint or nauseated after taking Prometrium, especially the 200 mg dose. It has been speculated by some holistic physicians, that the oil mixture is picked up by the lymphatics and somehow this causes the fainting reactions. I find that many women tolerate Prometrium but many others do not. I have not had these problems with either the Belmar Pharmacy Progesterone tablets or the capsules from local compounding pharmacies.

- Prometrium comes in only 100 mg and 200mg strengths. For women on low dose HRT I often use only 75 or 50mg of oral compounded progesterone. Occasionally, for PCOS patients, I go up to 150 mg of oral Progesterone capsules. Many women become too sleepy on the 200mg strength.