



Bioidentical Hormone Therapy: Custom Compounded versus Government Approved

Many types of hormone therapy are available for you to use for your menopause symptoms. These include hormones that are manufactured to be chemically identical to the naturally occurring hormones produced by your ovaries during the reproductive years, principally estradiol, progesterone, and testosterone. Many of these products are derived from natural sources, including yams or soy. Although the term *bioidentical hormones* often is used to refer to these identical copies of natural hormones (typically prescribed as custom mixes or compounds for an individual woman), *bioidentical hormones* is a term invented by marketers and has no clear scientific meaning.

Although natural hormones are not necessarily safer or more effective than other forms of estrogen and progesterone, some women prefer to use hormones after menopause that are identical to those their ovaries produced when they were younger.

If you prefer to treat your bothersome menopause symptoms with hormones that are chemically identical to those you produced naturally before menopause, ask your healthcare provider to prescribe estradiol and progesterone products that are scientifically tested and government approved. Estradiol is available as an oral tablet, skin patch, topical gel, topical spray, and vaginal ring. Low doses of estradiol used in the vagina (to treat vaginal dryness and painful intercourse but not hot flashes) are available as a vaginal tablet, cream, and ring. Progesterone is available as an oral capsule (see table below for product names).

Bioidentical custom-compounded hormones

Some healthcare providers prescribe custom-mixed (*custom-compounded*) bioidentical hormones containing one or more natural hormones mixed in differing amounts. These products not only contain the active hormone(s) but also other ingredients to create a cream, gel, lozenge, tablet, spray, or skin pellet. Healthcare providers who prescribe bioidentical hormones often claim that these products are more safe and effective than clinically tested and government-approved hormones produced by large pharmaceutical companies. They also may assert that bioidentical hormones slow the aging process. There is no scientific evidence to support any of these claims.

Government-approved hormone products are required by law to come with a package insert that describes possible risks and side effects. Custom-compounded hormones are not required to come with this information, but this does not mean they are safer. They contain the same active hormones (such as estradiol and progesterone), so they share the same risks.

Custom-compounded hormones allow for individualized doses and mixtures; however, this may result in reduced efficacy or greater risk. These compounds do not have government approval because individually mixed recipes are not tested to verify that the right amount of hormone is absorbed to provide predictable hormone levels in blood and tissue. If you have a uterus, there are no studies showing that the amount of progesterone in these custom-mixed hormones is enough to protect you from developing uterine cancer.

There is a long history of pharmacies providing a wide range of compounded products, typically when an equivalent government-approved product is not available. Because preparation methods vary from one pharmacist to another and between pharmacies, you may receive different amounts of active medication every time you fill the prescription. Inactive ingredients may vary from batch to batch as well. Sterile production technique and freedom from undesired contaminants are additional concerns. Expense is another issue, because most custom-compounded preparations are viewed as experimental drugs and are not covered by insurance plans.

Determining the right dose

The right dose of hormones for you is the lowest dose of estrogen that treats your menopause symptoms combined with enough progesterone to protect your uterus from cancer. It is not necessary to check blood, urine, or saliva hormone levels to find the right dose. During reproductive life, estrogen levels vary throughout the menstrual cycle and during each day, so there is no perfect hormone level for any woman.

Recommendations for natural hormone therapy options

If you prefer to use hormones for your menopause symptoms that are identical to the hormones you produced naturally before menopause, ask your healthcare provider for government-approved products containing estradiol and progesterone. There is no benefit to using custom-compounded hormones, and there may be additional risks.

Government-Approved Natural Hormone Therapy Products

Estradiol

Systemic doses of estradiol for treatment of hot flashes

- Oral tablet: Estrace, generics
- Skin patch: Alora, Climara, Esclim, Menostar, Vivelle (Dot), Estraderm, generics
- Skin gel/cream: EstroGel, Elestrin, Divigel, Estrasorb
- Skin spray: Evamist
- Vaginal ring: Femring

Low doses of vaginal estradiol for treatment of vaginal dryness and pain with intercourse

- Vaginal cream: Estrace vaginal cream
- Vaginal ring: Estring
- Vaginal tablet: Vagifem

Progesterone

- Oral tablet: Prometrium



This *MenoNote*, developed by the Consumer Education Committee of The North American Menopause Society, provides current general information but not specific medical advice. It is not intended to substitute for the judgment of a person's healthcare provider. Additional information can be found at www.menopause.org.

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