

## Bio-identical Hormones

The term “bio-identical hormones” (sometimes referred to as “natural hormones”) is used differently by different people. To scientists and healthcare providers, bio-identical hormones are those that are chemically identical to the hormones produced by women (primarily in the ovaries). A woman’s body can make various estrogens (such as 17-beta-estradiol, estrone, and estriol) as well as progesterone, testosterone, and other hormones. Thus, bio-identical hormone therapy can mean a medication that provides one or more of these hormones as the “active ingredient.”

Hormones have been produced commercially to be chemically exact duplicates of some of these naturally-occurring, bio-identical hormones. These hormones are made available in well-tested, government-approved, brand-name prescription drugs. Several drugs contain 17-beta-estradiol (Estrace and generic oral tablets, Estrace vaginal cream, all the estrogen skin patches, and now topical gels). There is one progesterone product (Prometrium oral capsules).

### Custom-compounded hormones

Many consumers and some healthcare providers believe that the term bio-identical hormone refers to a custom-mixed (“custom-compounded”) recipe containing one or more of various hormones in differing amounts, depending on an individual prescriber’s order. The recipe not only contains the active hormone (or hormones), but also other ingredients that either holds everything together (in the case of a rectal suppository, an under-the-tongue tablet, or an under-the-skin pellet) or provides a vehicle for applying the product onto the skin (such as a cream or gel) or into the body (such as a liquid for a nasal spray).

Custom-compounded hormones may provide certain benefits, such as individualized doses and mixtures of products and dosage forms that are not available commercially. However, there may be risks to the consumer. These compounds do not have government approval because individually mixed recipes have not been tested to prove that they are absorbed appropriately or provide predictable levels in blood and tissue. And there is no scientific evidence about the effects of these hormones on the body, both good and bad. Although there is a long history of pharmacies providing a wide range of compounded products, the fact that preparation methods vary from one pharmacist to another, and from one pharmacy to another, means that patients may not receive consistent amounts of medication. In addition, inactive ingredients may vary and there can be batch-to-batch differences. Reliable sterility and freedom from undesired contaminants are also concerns. Expense is also an issue, as many custom-compounded preparations are viewed as experimental drugs and are not covered by insurance plans.

### Hormone testing

Saliva testing to determine if a woman has the “right amount” of hormones has not been proven accurate or reliable. Even blood testing of hormone levels has the drawback that levels vary throughout the day as well as from day to day. More important, the desired levels in postmenopausal women have not been established. In addition, an individual woman’s physical comfort may not even be related to her absolute hormone levels.

### Recommendations

NAMS does not recommend custom-compounded products over well-tested, government-approved products for the majority of women – and does not recommend saliva testing to determine hormone levels.



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 an individual’s healthcare provider.

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