BIO-IDENTICAL HORMONE THERAPY

Is it natural? Is it better?



In your search for relief from the symptoms of menopause, you may have heard about natural or bio-identical hormone therapy. And you may be wondering whether these therapies are safe and effective. Here are some things to think about when considering this option in hormone therapy.

# What is bio-identical?

When something is "bio-identical," it is structurally identical to the naturally occurring substance in your body. Most bio-identical estrogens and progesterone come from soy (estrogen) or yams (progesterone). Once the hormones are extracted from the plant source, they are processed to be used by a woman's body, and are available by prescription in pills, patches or a gel, as well as compounded formulations. An important distinction is that this is not the same as herbal compounds, such as black cohosh, dong quai or other herbal remedies that are sometimes used by women during the menopause that are usually marketed as "natural" remedies.

# Is bio-identical better?

While there are no studies that show that bio-identical hormones are safer than synthetic hormones, many women prefer the types of hormones normally found in the body. These include bio-identical hormones such as estradiol (the primary estrogen produced by the ovary) and micronized progesterone. These bio-identical prescription products are similar to what the body made naturally prior to mid-life changes.

### MenopauseRx.com

# RECENT SURVEY FINDS THAT MOST WOMEN ARE UNSURE...

When asked about whether 'bio-identical' and 'natural' mean the same thing, nearly 40% of women who responded to a survey by MenopauseRx.com said 'no', and a little over 50% weren't sure.

Almost 35% feel that compounded hormone products are safer than FDA-approved options, and almost 60% weren't sure.

Nearly 70% weren't sure whether compounded hormone products are FDA-approved; yet more than 70% prefer an FDA-approved option and would be interested in an FDA-approved option.



# BIO-IDENTICAL HORMONE THERAPY IS AVAILABLE THROUGH:

FDA-APPROVED
PRESCRIPTION
PRODUCTS, SUCH
AS GELS, LOTIONS,
PATCHES AND PILLS.

NON-FDA-APPROVED
COMPOUNDED
PRODUCTS
PREPARED IN
SELECT
PHARMACIES.

# Bio-identical options.

If you're interested in bio-identical hormone therapy, there are several options available to you. These options allow you and your healthcare professional to tailor your therapy to your specific symptoms and medical history. They also allow you to choose a delivery method that fits your needs and preferences.

Estradiol is available by prescription in many FDA-approved estrogen products, including transdermal gels, lotions and patches, as well as oral tablets. Micronized progesterone for hormone therapy is available in FDA-approved capsules. Many of these products have been on the market for a number of years, and they commonly offer hormone formulations in varying dosages for symptom relief.

A complete list of these formulations can be found on MenopauseRx.com.

## The importance of choosing FDA-approved options.

Today, some pharmacies offer to custom-compound bio-identical hormone therapies for a woman's individual menopause symptoms. Commonly referred to as 'Triest'

or 'Biest', the active ingredient in these products is estradiol, the same active ingredient in FDA-approved prescription products. 'Triest' also contains estrone and estriol, while 'Biest' also contains estriol. Estrone and estriol are less potent estrogens normally produced by the

ovary prior to menopause.

Often, a saliva test is given to determine hormone levels, and formulations are customized based on the results. Caution is advised if you are considering this method of therapy for the following reasons\*:

#### Saliva tests are unreliable.

The concentration of hormones in saliva can vary widely depending upon diet, the time of day the test was performed, and the laboratory testing procedures.

# Safety and effectiveness cannot be assured.

While these compounded formulations may use FDA-approved ingredients like estradiol, the customized formulations are not approved and there are no guidelines for

their use. In addition, there are concerns regarding the purity, potency and quality of compounded products. In 2001, the FDA found that 9 out of 10 compounded products failed potency tests, and 34% failed one or more standard quality test.

<sup>\*</sup> The American College of Ob/Gyn (ACOG) states that 'there is no evidence that hormonal levels in saliva are biologically meaningful.' ACOG Committee Opinion Number 322, November 2005

Commercially available estradiol and progesterone products have withstood the rigors of FDA monitoring. When prescribed by your healthcare professional, these medications are usually covered by insurance companies. Conversely, insurance coverage for compounded products is quite variable and often subject to higher co-pays.

## So, is natural naturally better?

Research indicates that FDA-approved and prescribed bio-identical hormones are an effective way to alleviate the symptoms of menopause. Talk to your healthcare professional about this treatment option. And learn more about bio-identical therapy, and other treatments for menopause, by visiting www.MenopauseRx.com.



# SQUARE ONE: ARE HORMONES THE ANSWER?

The recent debates about hormone therapy have raged hotter than a hot flash. Recent research, including studies from the Women's Health Initiative, has put the use of hormone therapy in question. As always, talking to your healthcare professional is the best way to evaluate all the risks and benefits.

Estrogens with or without progestins should
not be used to prevent
heart attacks or heart
disease. In clinical
studies, estrogens given
in combination with
progestins have been
reported to increase
the risk of heart attacks,
stroke, breast cancer
and blood clots in
menopausal women.

It might help to know that hormone therapy remains the standard of care for relief of troublesome menopause symptoms. So if you decide to use it, you are not alone. But because of its risks, The North American Menopause Society recommends using the lowest dose of hormone for the shortest time to relieve symptoms.

# Topical progesterone creams and gels: A look beneath the surface.

Touted as a way to relieve hot flashes, osteoporosis, and a myriad of other health claims, topical progesterone creams and gels are available as over-the-counter (OTC) products or custom-compounded by prescription.

The primary reason physicians prescribe progesterone during menopause is to protect the lining of the uterus in women who have not had a hysterectomy and are taking estrogen therapy.

Topical OTC and compounded progesterone creams and gels may not sufficiently protect the uterine lining when taken with estrogen as part of a hormone regimen and could lead to an abnormally thickened lining called endometrial hyperplasia. Endometrial hyperplasia can be associated with abnormal, heavy vaginal bleeding and pre-cancerous changes within the uterus. Therefore, MenopauseRx.com does not recommend their use as part of a hormone regimen.



## Advice from MenopauseRx.com.

If you choose to use hormones, MenopauseRx.com recommends reviewing with your healthcare professional, each year, the reason why therapy was started. Most women find that, over time, the symptoms of menopause diminish, or the reasons to use hormone therapy change. As that happens, it is beneficial to gradually lower your dose, and eventually discontinue the use of hormones.