

## **HORMONE REPLACEMENT THERAPY WITH BIO-IDENTICAL HORMONES**

### **What are bio-identical hormones?**

Bio-identical hormones have a chemical structure identical to human hormones but are chemically synthesized, such as progesterone, estriol, and estradiol. Non-bio-identical hormones are not structurally identical to human hormones and may either be chemically synthesized, such as medroxy-progesterone acetate, or derived from a non-human source, such as conjugated equine estrogens<sup>(1)</sup>.

### **Why should one consider HRT (Hormone replacement Therapy)?**

- Relief of symptoms
- Prevention of memory loss
- Heart health
- Bone production (prevention of osteoporosis)
- Growth and repair
  - Hormones that regulate growth and repair
    - Insulin
    - Growth hormone
    - Testosterone
    - Estrogens
    - DHEA

### **Hormone replacement therapy with bio-identical hormones can be started after:**

1. Underlying adrenal fatigue or stress have been treated.
2. A good symptomatology history to assess hormonal deficiencies/excesses (see questionnaire) has been taken.
3. Any hormonal cancers (Ca125, Ca153, CEA, breast examination, sonar, mammogram, ovarian and endometrial sonar) have been ruled out.
4. Risks for breast cancer has been established.
5. Blood tests or saliva tests to assess the hormonal status have been done.

Hormone response is as unique to each person as their own fingerprints. Hormone replacement should not be considered without a thorough understanding of how all the body's hormones interact with each other.

## **What is menopause?**

Menopause is defined as no menstrual cycle for 12 months. Symptoms, however, can begin as long as fifteen years prior to menopause. The normal age to go through menopause ranges from 35 to 55. Therefore, women may easily live on half of their lives without a menstrual cycle<sup>(2)</sup>.

Until recently , the only hormonal therapy available has been synthetic hormone replacement. A Women's Health Initiative (WHI) Program which was sponsored by the USA government on the study of estrogen plus progestin (synthetic non-bio-identical progesterone) was halted in 2002. This study was halted three years early because of the increased risk of breast cancer in women taking these hormones<sup>(3)</sup>. Analysis of the study also revealed that heart attack risk began increasing in the progestin group early in the study which was conducted on 16 000 women who had not had a hysterectomy. Participants in the study were either given synthetic progesterone or a placebo. The results of this study highlights the problems associated with "one-size fits all" medicine. HRT should not be a one-size fits all approach.

**Natural hormone replacement – the use of hormones that are biologically identical to what one's body makes.**

## **THE USE OF VARIOUS OESTROGENS**

Oestrogen is primarily made by the ovaries and consists of a combination of three compounds: estrone (E1), estradiol (E2) and estriol (E3). In the suggested cycling protocol below, E2 cream can be used alone, but there are clear advantages in using Bi-Est cream which consists of two naturally occurring oestrogens: estriol and estradiol. Considerable evidence exists to show that estriol protects against breast cancer. Estradiol protects the bones, heart and brain.

For more information go to:

<http://www.imcmed.co.za/articals/Fellowship%20Position%20Paper%20of%20Hormone%20Measurement%20and%20Replacement%20-%208-4-09.pdf>

**Hormone symptoms in peri-menopause & menopause:**

<b>SYMPTOMS</b>	<b>ESTROGENS</b>	<b>PROGESTERONE</b>	<b>TESTOSTERONE</b>
Fibrocystic breast	High	Low	=
Weight gain	High	Low	=
Heavy menstrual bleeding	High	Low	=
Dry skin/hair	Low	Low	=
Hot flushes	Low	=	=
Anxiety	High/Low	High	=
Depression	Low	=	Low
Night sweats	Low	=	=
Vaginal dryness	Low	=	Low
Headaches	High/Low	High/Low	Low
Irritability	High	High/Low	=
Mood swing	High	Low	=
Breast tenderness	High	High/Low	=
Sleep disturbances	Low	Low	High
Fluid retention	High	Low	=
Breakthrough bleeding	High	Low	=
Fatigue	Low	High	Low
Loss of memory	Low	=	Low
Bladder symptoms	Low	=	Low
Harder to reach climax	Low	Low	Low
Decreased libido	High	=	Low
Hair loss	High/Low	High/Low	High

**The following is a suggested treatment protocol based on symptoms, blood-tests and if all contra-indications have been ruled out:**

**1. BIO-IDENTICAL PROGESTERONE:**

See Patient Information Leaflet for directions for application of the cream and for cycling regime.

<http://www.imcmed.co.za/pdf/Progesterone%2010%2002%2009.pdf>

<b>SEVERE SYMPTOMS</b>	<b>MODERATE SYMPTOMS</b>	<b>MILD SYMPTOMS</b>
Fatigue Estrogen dominance Moderate hot flushes Moderate night sweats Anxiety Breast tenderness Weight gain Palpitations Irregular frequent heavy Periods	Mild fatigue Hot flushes Night sweats Anxiety Unable to lose weight Periods frequent and heavy flow	Night sweats Periods more frequent, not heavy Symptoms worsen last 2 weeks of cycle

<b>PREMENOPAUSAL from age 28:</b> Progesterone cream: Apply from day 10-25 *	<b>POSTMENOPAUSAL :</b> Progesterone cream: Apply from day 1-25 *
<i>Severe symptoms:</i> Progesterone cream 3%: 1 (1ml) scoop at night Or Progesterone capsules per mouth: Take 2 capsules at night (200 mg)	<i>Severe symptoms:</i> Progesterone cream 3%: 1 (1ml) scoop at night Or Progesterone capsules per mouth: Take 2 capsules at night (200 mg)
<i>Moderate symptoms:</i> Progesterone cream 3%: ½ to 1 scoop at night Or Progesterone capsules per mouth: Take 2 capsules at night (200 mg)	<i>Moderate symptoms:</i> Progesterone cream 3%: ½ to 1 scoop at night Or Progesterone micronized per mouth: Take 2 capsules at night (200 mg)
<i>Mild symptoms:</i> Progesterone cream 3%: ½ (0.5ml) scoop at night Or Progesterone capsules per mouth: Take 1 capsule at night (100 mg)	<i>Mild symptoms:</i> Progesterone cream 3%: ½ (0.5ml) scoop at night Or Progesterone micronized per mouth: Take 1 capsule night (100 mg)

\* Working on a 28 day cycle

Progesterone cream 3% (transdermal) is available from doctors, selected pharmacies, Dis-Chem pharmacies, health stores or from SOLAL Technologies.

Progesterone cream can be increased up to 4%, 5%, 10% - Available from The Compounding Pharmacy of South Africa.

Oral Progesterone capsules (micronized) should be the first option for adrenal stress, anxiety or Insomnia.

Oral Progesterone capsules (micronized) are available from The Compounding Pharmacy of South Africa.

011 463 0310

## 2. BIO-IDENTICAL ESTROGEN : BI-EST cream:

See Patient Information Leaflet for directions for application of the cream

<b>SEVERE SYMPTOMS</b>	<b>MODERATE SYMPTOMS</b>	<b>MILD SYMPTOMS</b>
Younger and more severe hot flushes Periods ceased or less frequent Fatigue Dry skin,mouth,vagina Mood swings Osteopenia Severe depression Lack of energy after 6pm	Severe hot flushes and Night sweats Mild fatigue Periods lighter and more infrequently Mood swings Depression Apathy Hairloss - crown of head Droopy, dry skin	Some hot flushes Night sweats More periods in frequency but not heavy Irritable Depression

<b>PRE-MENOPAUSAL:</b> Apply from day 1-25 *	<b>MENOPAUSAL:</b> Apply from day 1-25 *	<b>ELDERLY or ESTROGEN DOMINANCE:</b> Apply from day 1-25 * (PMS, Cysts, Fibroids, etc.)
<i>SEVERE SYMPTOMS:</i> BI-EST 50:50 Or BI-EST 60:40 Or BI-EST 80:20 1 (1ml) scoop in the morning	<i>SEVERE SYMPTOMS:</i> BI-EST 60:40 1 (1ml) scoop in the morning	<i>SEVERE SYMPTOMS:</i> BI-EST 80:20 1 (1ml) scoop in the morning
<i>MODERATE SYMPTOMS:</i> BI-EST 60:40 1 (1ml) scoop in the morning	<i>MODERATE SYMPTOMS:</i> BI-EST 80:20 1 (1ml) scoop in the morning	<i>MODERATE SYMPTOMS:</i> BI-EST 80:20 ½ (0.5ml) scoop in the morning
<i>MILD SYMPTOMS:</i> BI-EST 80:20 1 (1ml) scoop in the morning	<i>MILD SYMPTOMS:</i> BI-EST 80:20 ½ (0.5ml) scoop in the morning	<i>MILD SYMPTOMS:</i> BI-EST 80:20 ½ (0.5ml) scoop in the morning

\* Working on a 28 day cycle

Bi-Est cream (transdermal) - Available from The Compounding Pharmacy of South Africa.  
Only available on prescription.

### 3. **BIO-IDENTICAL TESTOSTERONE cream :**

TESTOSTERONE cream for women : from 0,125% - 0,25% to maximum of 0,50%

Based on symptoms and blood tests:

See Patient Information Leaflet for directions for application of the cream.

<http://www.imcmed.co.za/pdf/Testosterone%20PIL%208.05.09.pdf>

Testosterone cream (transdermal) - Available from The Compounding Pharmacy of South Africa.

Only available on prescription.

TESTOSTERONE cream for men: from 2.5% - 5% to a maximum of 10%

Based on symptoms and blood tests:

See Patient Information Leaflet for directions for application of the cream.

<http://www.imcmed.co.za/pdf/Testosterone%20PIL%208.05.09.pdf>

Testosterone cream (transdermal) - Available from The Compounding Pharmacy of South Africa.

Only available on prescription.

## **BIO-IDENTICAL HORMONES AND PMS**

### **WHAT IS PMS (Pre-Menstrual Syndrome)?**

PMS is a HORMONAL DISORDER characterized by the monthly recurrence of certain physical or psychological symptoms during the 2 weeks before menstruation and the subsiding of those symptoms when menstrual flow begins or slightly afterwards.

### **COMMON PMS SYMPTOMS:**

Abdominal bloating - Backache - Breast tenderness - Constipation - Cramps - Fatigue - Dizziness - Depression - Headaches - Hot flashes - Irritability - Nausea - Insomnia - Tension - Tremors - Vomiting - Weight gain - etc...

### **BIO-IDENTICAL HORMONE THERAPY OF PMS :**

PROGESTERONE cream 3% : Apply ½ (0.5ml) scoop twice a day from day 10 to day 25 of cycle.

As long as you experience PMS symptoms, you aren't taking enough progesterone. The creams can be increased to 4%, 5%, 10%. - Available from The Compounding Pharmacy of South Africa.

Or you can use Progesterone capsules (micronized): Take 1 capsule at night. You can increase the dose to 2 capsules at night.

Most women with severe PMS do not even respond to 10% Progesterone creams.

### **OTHER NUTRACEUTICALS AVAILABLE FOR TREATMENT OF PMS :**

- Soy Isoflavones: Take 1 capsule daily, with or shortly after a meal
- Krill Oil (Neptune - NKO®) Omega 3 (or Fish Oil Extract Omega 3 or Sol-Oil 3 & 6 or Flaxseed Oil Omega 3): Take 1 capsule twice daily, with or shortly after meals
- Magnesium Glycinate: Take 2-4 capsules at night, with or shortly after a meal
- St. John's Wort: Take 1 capsule two to three times per day after meals
- Hormone Balance Natural HRT: Take 2 capsules daily after a meal
- Vitamin A: Take 1 tablet daily after a meal
- Super Mega-B™: Take 1 capsule twice daily, with or shortly after meals
- Parsley or strawberries (natural diuretics)

## **BIO-IDENTICAL HORMONES AND ENDOMETRIOSIS**

In endometriosis, pieces of endometrium, the typical mucous membranes of the inner wall of the uterus, develop in unexpected places such as the ovaries, the colon and the external sides of the uterus.

As *Progesterone* is responsible for keeping endometrial growth at normal levels, progesterone deficiency in the presence of normal estrogen levels is accompanied by excessive proliferation of the endometrium, which in turn predisposes women to endometriosis.

As *Thyroid Hormone* and *Cortisol* deficiencies may cause progesterone deficiency, we recommend also to screen and treat these deficiencies first or simultaneously with *Progesterone* treatment.

### **SYMPTOMS OF ENDOMETRIOSIS:**

- Abnormal pelvic pain and pain during intercourse (2-3 days before menstruation and during the menstrual flow)
- Abnormal vaginal bleeding
- Constipation or diarrhoea
- Frequent urination
- Blood in the stool or urine
- Nausea, vomiting and fainting spells
- Infertility

### **DIAGNOSIS OF ENDOMETRIOSIS:**

- Laparoscopy and biopsy
- Magnetic resonance imaging and ultrasound for larger lesions
- Ca 125 : elevated in blood test

### **BIO-IDENTICAL HORMONE TREATMENT OF ENDOMETRIOSIS :**

PROGESTERONE 3% cream : Apply  $\frac{1}{4}$  (0.25ml) to  $\frac{1}{2}$  (0.5ml) scoop of cream twice a day from day 15 to day 25 of cycle.

Or Micronized progesterone 100 mg capsule : Take 1-2 capsules at night from day 12 or day 15 to day 23-25 of cycle.

In severe endometriosis : PROGESTERONE 3% cream : Apply  $\frac{1}{4}$  (0.25ml) scoop twice a day from day 5 to day 14 and  $\frac{1}{2}$  (0.5ml) scoop twice a day from day 15 to day 25 of cycle.

The dose can be increased until the pelvic pain stops.

**OTHER NUTRACEUTICALS AVAILABLE FOR THE TREATMENT OF ENDOMETRIOSIS:**

- Krill Oil (Neptune - NKO®) Omega 3 (or Fish Oil Extract Omega 3 or Sol-Oil 3 & 6 or Flaxseed Oil Omega 3): Take 1 capsule twice daily, with or shortly after meals
- Double Vitamin C™: Take 3 capsules daily, with or after meals
- Full Spectrum Vitamin E: Take 1 capsule daily, with or shortly after a meal
- Milk Thistle Extract: Take 1 capsule daily
- Indole 3 Carbinol: Take 1 capsule daily

AVOID PHYTOESTROGENS and PLANT-BASED ESTROGENS, found in soy products in endometriosis.

## **BIO-IDENTICAL HORMONES AND PCOS**

### **WHAT IS PCOS (Polycystic ovary syndrome)?**

PCOS is a condition which includes:

- Irregular or absence of menstruation
- Excess of androgen production
- Lack of other reasons for irregular or absence of cycles and excess androgens

### **SYMPTOMS OF PCOS:**

- Obesity
- Irregular or absence of menstrual cycles
- Infertility / recurrent miscarriage
- Hirsutism
- Oily skin / acne
- Alopecia
- Depression

### **LABORATORY AND SONAR :**

- Cysts on the ovaries (sonar)
- Blood : High testosterone level or high DHEA or high androstenedione
- Elevated insulin level or insulin resistance
- Elevated LH
- Decreased SHBG
- Abnormal lipid profile
- Hypertension

### **BIO-IDENTICAL HORMONE THERAPY IN PCOS:**

PROGESTERONE 3 % cream : Apply ½ (0.5ml) scoop twice a day from day 10-25 of cycle.

Dose can be increased based on the symptoms and blood tests.

Or Micronized Progesterone capsules 100 mg: Take 1 capsule at night.

## **OTHER NUTRACEUTICALS FOR THE TREATMENT OF PCOS:**

- NEW: d-Chiro-Inositol: Take 1-2 capsules twice daily, with or shortly after meals
- Alpha Lipoic Acid (Dual R-form) (or Alpha Lipoic Acid): Take 1 capsule daily, with or without a meal
- Chromium Polynicotinate: Take 1 tablet twice daily with meals
- Beta-Sitosterol: Take 1 capsule twice daily
- Hormone Balance Natural HRT: Take 2 capsules daily after a meal
- Soy Isoflavones: take 1 capsule daily with or shortly after a meal
- Burnout™: Take 1 capsule twice daily with a meal (Refer to label for directions for use)
- Invisible Fibre™: Refer to label for directions for use
- Stress Damage Control: Take 1 capsule after breakfast and 1 capsule after lunch
- Krill Oil (Neptune - NKO®) Omega 3 (or Fish Oil Extract Omega 3 or Sol-Oil 3 & 6 or Flaxseed Oil Omega 3): Take 1 capsule twice daily, with or shortly after meals
  
- Treatment of Insulin resistance :
  - Alpha Lipoic Acid (Dual R-Form): Take 1 capsule daily, with or without a meal
  - Chromium Polynicotinate: Take 1 tablet three times per day with meals
  - CLA: Take 1 capsule three times per day, 30 minutes before meals
  - Magnesium Glycinate: Take 2 capsules at night after a meal

### **References:**

1. K, H. (January 2009). The Bioidentical Hormone Debate: Are Bioidentical Hormones (Estradiol, Estriol, and Progesterone) Safer or More Efficacious than Commonly Used Synthetic Versions in Hormone Replacement Therapy? *Postgraduate Medicine, Volume 121, issue 1* .
2. Smith, P. HRT: The Answers. 2003.
3. Writing Group for the Women's Health Initiative Investigators, "Risk and benefit of estrogen plus progestin in healthy post-menopausal women," *JAMA* 2002; 288:321-333.

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