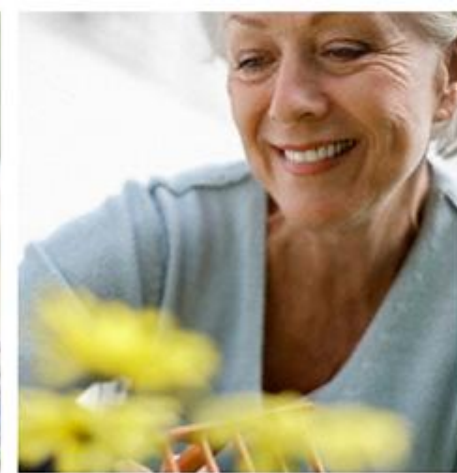


# New Perspectives, New Choices



Current practice in treating the  
symptoms of menopause

# What We're Going to Talk About Today

- ❑ Perimenopause and menopause are natural phases of your life
- ❑ The physical and psychological changes may have a real impact
- ❑ Work with your healthcare professional to understand your options, balance the benefits and risks of treatment, and make the best choice for you and your lifestyle



# Evaluate Yourself

← **Not a Problem** **Severe Problem** →

Hot Flashes	1	2	3	4	5	6	7	8
Night Sweats	1	2	3	4	5	6	7	8
Mood Swings	1	2	3	4	5	6	7	8
Forgetfulness	1	2	3	4	5	6	7	8
Energy Level	1	2	3	4	5	6	7	8
Sexual Function/Pain	1	2	3	4	5	6	7	8
Skin Quality	1	2	3	4	5	6	7	8
Facial Hair	1	2	3	4	5	6	7	8
Quality of Sleep	1	2	3	4	5	6	7	8
Urinary Problems	1	2	3	4	5	6	7	8
Other Pain	1	2	3	4	5	6	7	8





# Perimenopause and Menopause

Who, What, When, Why, and How?



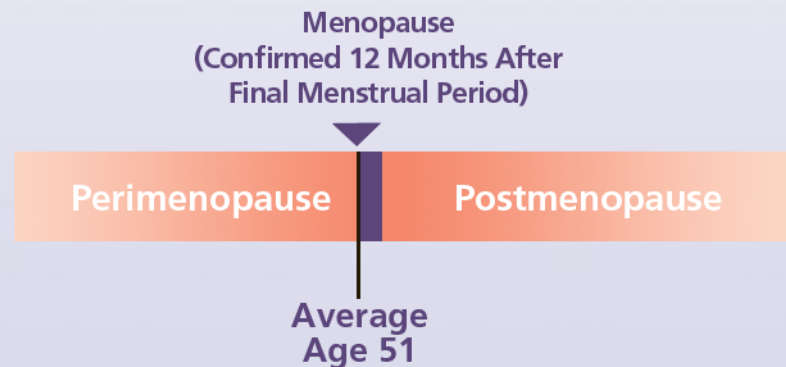
# WHO Is Affected by Menopause?

- ▣ It's part of the natural progression of a woman's life
- ▣ While every woman experiences menopause, each woman's experience is unique



# WHAT Is Menopause?

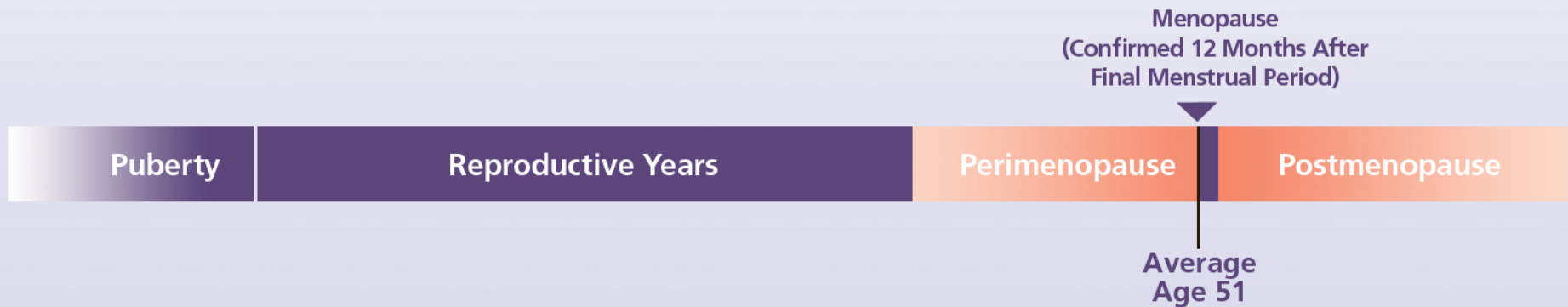
- ❑ Confirmed when you've experienced 12 consecutive months *without* a menstrual period
- ❑ Freedom from birth control
- ❑ An opportunity to improve health practices and enhance your sense of well-being
- ❑ Most women live at least one-third of their lives after menopause period-free



# WHEN

## Does Menopause Start?

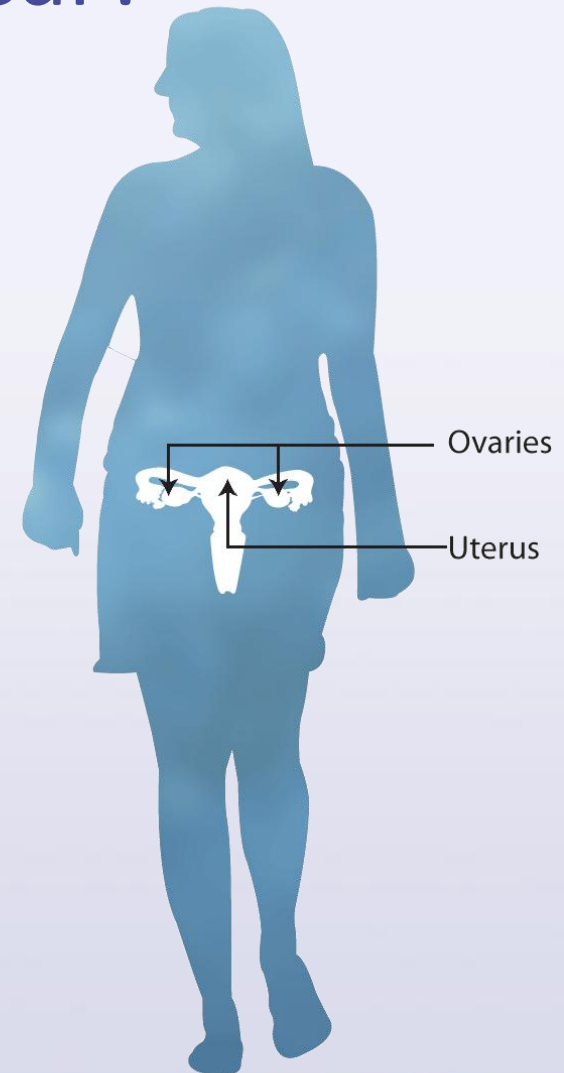
- ❑ Menopause typically occurs between the ages of 40 and 58 (average age is 51)
- ❑ Menopause is preceded by a transitional time called perimenopause
  - ❑ It can last 6 years or more
  - ❑ Most women report 4 to 8 years of menstrual cycle changes
  - ❑ Some women begin to experience symptoms like hot flashes
- ❑ The postmenopausal phase refers to the years following menopause



# WHY

## Does Menopause Occur?

- ❑ Naturally occurs when the ovaries stop producing estrogen and progesterone
- ❑ May also occur when the uterus and ovaries are surgically removed (total hysterectomy or bilateral oophorectomy)



# HOW Does Menopause Occur?

- ❑ Estrogen is a hormone produced by the ovaries that plays a role throughout the body, in maintaining skin, hair, and bone health, for example
- ❑ As you approach menopause, estrogen levels fluctuate
- ❑ Your menstrual cycle and bleeding patterns change
- ❑ Menstrual cycles may become irregular—longer, shorter, or altogether absent
- ❑ Bleeding patterns may become heavier or lighter





# Not Feeling Like Yourself?

A Closer Look at Symptoms



# A Range of Signs and Symptoms

## Symptoms directly linked to menopause

- ❑ Hot flashes
- ❑ Night sweats, which may result in sleep disturbances
- ❑ Vaginal dryness

## Common complaints reported around menopause

- ❑ Mood swings, depression, anxiety
- ❑ Lack of concentration, forgetfulness
- ❑ Skin dryness/loss of elasticity
- ❑ Joint pain
- ❑ Weight gain
- ❑ Thinning hair
- ❑ Pain during sex/loss of sex drive
- ❑ Urinary incontinence





# A Flash From the Past...and a Promising Future

The Evolution of Treatment Options for Menopause



# Menopause Treatments Through the Years



1960s



1970s

WHI

2002

Low-Dose  
and Localized  
Options

2004



Gel and  
Transdermal  
Options



# A Historical Look at Treatment

- ❑ Since the 1940s, millions of women have received hormone therapy (HT)
- ❑ HT was viewed as “natural,” giving the body back something it had become deficient in (estrogen)
- ❑ HT was and still is proven to relieve vasomotor menopausal symptoms: hot flashes and night sweats
- ❑ Prior to WHI, HT was thought to prevent heart disease, osteoporosis, and cancer, as well as improve a woman’s quality of life
- ❑ Two medications were commonly given:
  - ❑ Premarin<sup>®</sup>: an estrogen
  - ❑ Prempro<sup>®</sup>: a combination of estrogen and progestin



# What's a Woman to Do?

- ❑ In 2002, news reports from a study of hormone therapy began to appear
- ❑ Women were in for a roller-coaster ride of conflicting information...



# Hormone Therapy in the Media

**2002**

U.S. Stops Study on  
Hormone Therapy

by Rita Rubin, USA TODAY

**2006**

On 2nd Thought, Estrogen  
Can Help: Safe Window Found  
for Hormone Therapy

by Judy Peres, CHICAGO TRIBUNE

**2003**

Hormone Therapy Undergoes  
Rise and Fall

by Stephen Smith, THE BOSTON GLOBE

**2007**

A Boost for Hormone  
Therapy

by Alice Park, TIME

**2004**

New Hormone Therapy Risks Study:  
Additional Risks for Women on  
Estrogen-Alone Therapy

by Rome Neal, CBS NEWS, THE EARLY SHOW

**2008**

Hormone Therapy Safe,  
Effective for Women  
Entering Menopause

FORBES.COM

**2005**

Hormone Therapy Tied to  
More Severe Strokes

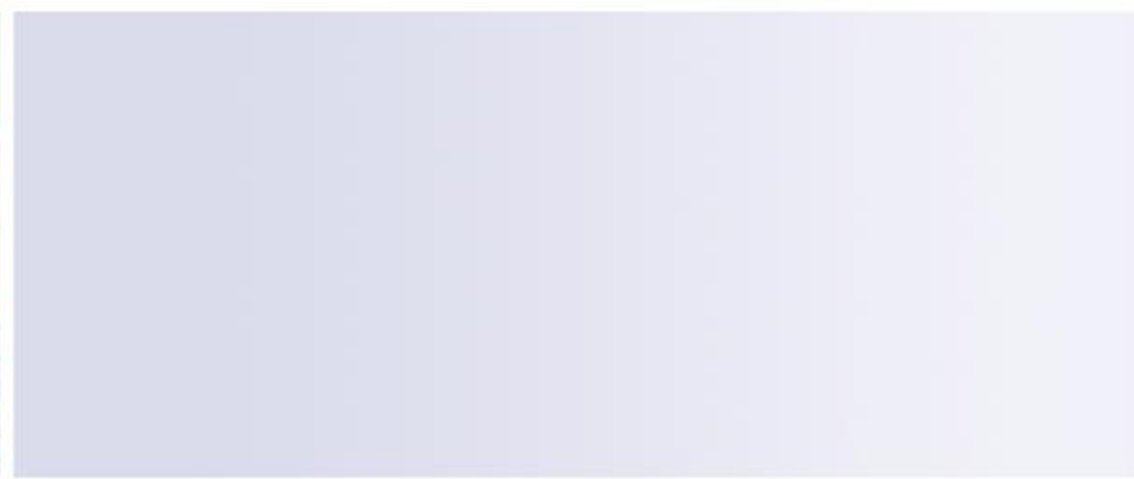
by Miranda Hitti, FOX NEWS

**2009**

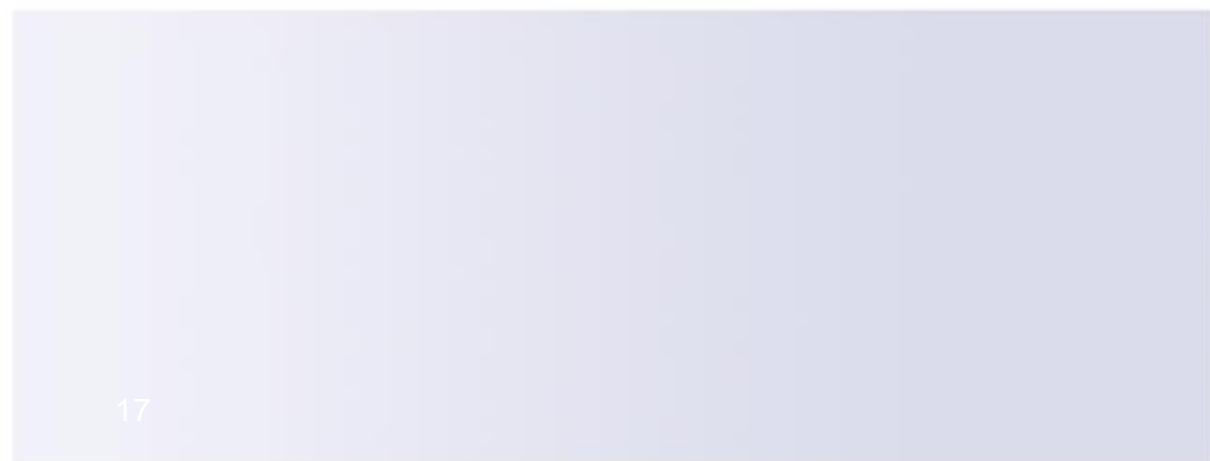
Hot Flash: Hormone Therapy is  
Back

by Naomi Barr, OPRAH.COM





# Findings From the WHI



# The Women's Health Initiative (WHI)

A landmark research initiative that started in 1991; over 27,000 women enrolled in the Hormone Therapy Trial.

- ❑ Set out to evaluate what effect menopausal hormone therapy would have on heart disease prevention, breast and colorectal cancer, bone cancer, and other outcomes
- ❑ Did not evaluate effectiveness of hormone therapy as treatment for menopausal symptoms
- ❑ Treatment included placebo, estrogen alone (Premarin<sup>®</sup>), or estrogen + progestin (Prempro<sup>®</sup>) once daily for a planned 8 years
- ❑ Women receiving estrogen alone were found to be at an increased risk for stroke and blood clot
- ❑ Women receiving estrogen + progestin experienced an increased risk for breast cancer and heart disease, among other findings
- ❑ Study caused healthcare community to rethink hormone therapy
- ❑ Led to positive changes in treatment options and practices



# WHI: Treatment

**10,739 Women With a Hysterectomy**

Estrogen (Premarin<sup>®</sup>)

or

Placebo

**16,608 Women With an Intact Uterus**

Estrogen + Progestin (Prempro<sup>®</sup>)

*or*

Placebo



# Putting the WHI Results Into Perspective (Estrogen Alone)

Outcome	Number of events per year per <b>1,000</b> women taking placebo	Number of events per year per <b>1,000</b> women taking estrogen-alone therapy	Difference in risk compared with placebo
Coronary Heart Disease	<b>5.4</b>	<b>4.9</b>	<b>-0.5</b> fewer women experienced coronary heart disease <sup>a</sup>
Breast Cancer	<b>3.3</b>	<b>2.6</b>	<b>-0.7</b> fewer women had breast cancer <sup>a</sup>
Hip Fracture	<b>1.7</b>	<b>1.1</b>	<b>-0.6</b> fewer women had hip fractures
Vertebral Fracture	<b>1.7</b>	<b>1.1</b>	<b>-0.6</b> fewer women had vertebral fractures
Venous Thromboembolism (blood clots)	<b>1.5</b>	<b>2.1</b>	<b>+0.6</b> more women had blood clots
Colorectal Cancer	<b>1.6</b>	<b>1.7</b>	<b>+0.1</b> more women had colorectal cancer <sup>a</sup>
Stroke	<b>3.2</b>	<b>4.4</b>	<b>+1.2</b> more women experienced stroke

<sup>a</sup>No statistical difference.



# WHI: Estrogen + Progestin

Outcome	Number of events per year per <b>1,000</b> women taking placebo	Number of events per year per <b>1,000</b> women taking estrogen+progestin therapy	Difference in risk compared with placebo
Hip Fracture	<b>1.5</b>	<b>1.0</b>	<b>-0.5</b> fewer women had hip fractures
Colorectal Cancer	<b>1.6</b>	<b>1.0</b>	<b>-0.6</b> fewer women had colorectal cancer
Heart Attack	<b>3.0</b>	<b>3.7</b>	<b>+0.7</b> more women experienced heart attacks
Breast Cancer	<b>3.0</b>	<b>3.8</b>	<b>+0.8</b> more women had breast cancer
Stroke	<b>2.1</b>	<b>2.9</b>	<b>+0.8</b> more women experienced stroke
Venous Thromboembolism (blood clots)	<b>1.6</b>	<b>3.4</b>	<b>+1.8</b> more women had blood clots



# After the WHI

## Boxed Warning:

Applies to all estrogen therapies that treat hot flashes and vaginal symptoms, regardless of type, delivery, and dose

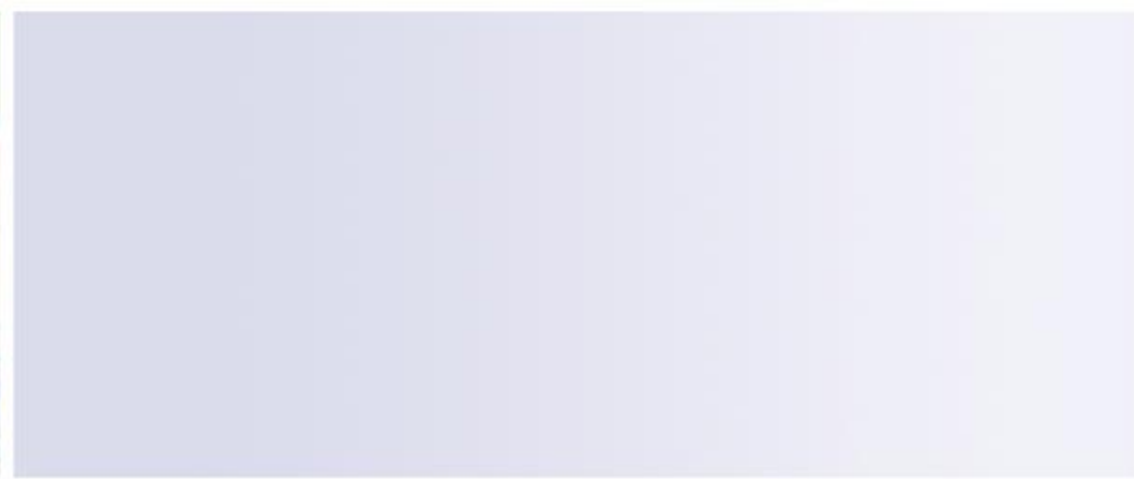
- ❑ Increased risk of cancer of the uterus
- ❑ Increased risk of heart attacks, strokes, breast cancer, and blood clots
- ❑ Increased risk of dementia
- ❑ Talk regularly with your healthcare professional about whether you still need treatment



# After the WHI

- ❑ Estrogen is an effective treatment for hot flashes, night sweats, vaginal dryness, and prevention of osteoporosis
- ❑ It's important to weigh the benefits and risks
- ❑ With all the variables that must be considered—personal and family histories, lifestyle—individualizing treatment is critical
- ❑ The FDA has approved newer therapies, including bioidenticals, that offer lower doses to treat specific menopausal symptoms





# Know Your Options

Treatment Comes in Many Different Forms



# Educate Yourself, Empower Yourself

**Find out what's right for you,  
your lifestyle, your body,  
and your symptoms**



# Lifestyle Changes

- ❑ Avoid triggers
- ❑ Stay as cool as possible
- ❑ Exercise
- ❑ Practice relaxation techniques



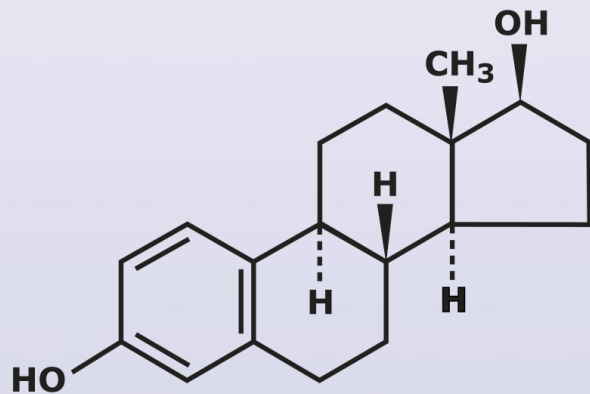
# Hormone Therapy

- ❑ Prescription hormone therapies—estrogen alone or in combination with progestin—are the only proven and approved treatments for hot flash/night sweat relief. There are many options, including:
  - ❑ Bioidentical and FDA-approved estrogens
  - ❑ Custom-compounded hormones (not FDA-approved)

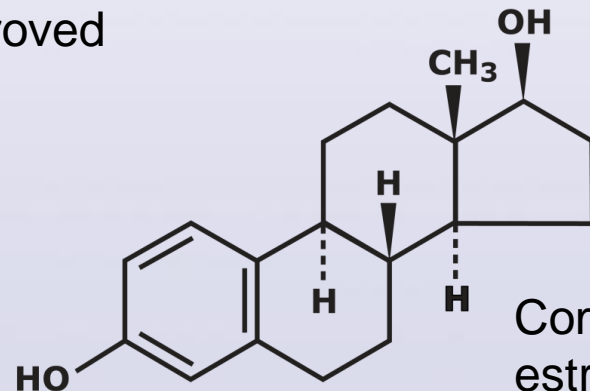


# What Is Bioidentical Estrogen?

- ❑ Chemically identical to the estrogen produced by women naturally (primarily in the ovaries) before menopause
- ❑ Commonly derived from plant sources
- ❑ Some bioidentical prescriptions are well-known FDA-approved brands
- ❑ Look for an accompanying package insert or prescribing information to ensure the product is FDA-approved



FDA-approved  
estradiol



Compounding  
estradiol



# Custom-Compounded Hormones

- ❑ Some custom-compounded formulations—made using chemical “recipes”—are also called bioidentical
- ❑ Custom-compounded hormones offer the benefit of individually tailored doses and mixing of different hormones
- ❑ Custom-compounded formulations are not FDA-approved and have not been tested for purity, potency, efficacy, or safety
- ❑ However, some active ingredients may be available in some FDA-approved products



# Current FDA-Approved Delivery Options

Hormone treatment comes in several different formulations:

- ❑ **Oral tablets** (Activella<sup>®</sup>, Angeliq<sup>®</sup>, Cenestin<sup>®</sup>, Enjuvia<sup>™</sup>, Estrace<sup>®</sup>, Femhrt<sup>®</sup>, Femtrace<sup>®</sup>, Menest<sup>®</sup>, Ortho-Est<sup>®</sup>, Prefest<sup>®</sup>, Premarin<sup>®</sup>, Premphase<sup>®</sup>, Prempro<sup>®</sup>)
- ❑ **Vaginal preparations** (Estrace<sup>®</sup> Vaginal Cream, Estring<sup>®</sup>, Femring<sup>®</sup>, Premarin<sup>®</sup> Vaginal Cream, Vagifem<sup>®</sup>)
- ❑ **Transdermal preparations**
  - ❑ Gels (Divigel<sup>®</sup>, Elestrin<sup>™</sup>, EstroGel<sup>®</sup>)
  - ❑ Lotion (Estrasorb<sup>®</sup>)
  - ❑ Spray (Evamist<sup>™</sup>)
  - ❑ Patches (Alora<sup>®</sup>, Climara<sup>®</sup>, Climara Pro<sup>®</sup>, Combipatch<sup>®</sup>, Esclim<sup>®</sup>, Estraderm<sup>®</sup>, Menostar<sup>®</sup>, Vivelle-Dot<sup>®</sup>)



# A Word About Oral and Vaginal Medication Delivery

- ❑ Oral estrogen must first pass through your liver before it exposes your entire body to medication
- ❑ Vaginal preparations may act locally or throughout your body by entering your system through the vaginal membrane
  - ❑ Vaginal preparations that act locally are not indicated for hot flashes
  - ❑ If estrogen is prescribed for vaginal symptoms only, local preparations should be considered



# The Benefits of Delivery Through the Skin (Transdermal)

- ❑ Allows estrogen to be absorbed through the skin and enter the bloodstream directly
- ❑ Bypasses the digestive system
- ❑ Avoids first-pass metabolism by the liver, allowing for lower doses of drug
  - ❑ The possibility of fewer side effects
- ❑ Fewer fluctuations in hormone concentrations in the blood than seen with oral drugs, resulting in relatively level concentrations
- ❑ Convenient



# “Natural” Remedies

- ❑ Commonly used supplements include
  - ❑ Soy, isoflavones (other plant estrogens)
  - ❑ Black cohosh
- ❑ Scientific evidence is often not reviewed by the FDA
- ❑ Not tightly regulated
- ❑ Relief may be due in part to a placebo effect
- ❑ Not risk-free
- ❑ Untold amounts of money are spent on these remedies, instead of on prescription medications that are proven to work





# Finding What's Right for You

## Are You a Candidate for Estrogen Therapy?



# Who SHOULD Consider Hormone Therapy?

Hormone therapy may be considered for women who:

- ❑ Are experiencing moderate to severe hot flashes
  - ❑ These include night sweats, which can cause frequent waking and other sleep disturbances
- ❑ Have vaginal dryness or irritation
- ❑ Need to prevent postmenopausal osteoporosis and are at significant risk of osteoporosis\*

\*Careful consideration should be given to nonestrogen therapies.



# Common Estrogen Side Effects

These are side effects that are commonly reported:

- ❑ Uterine bleeding (starting or returning)
- ❑ Breast tenderness or pain (increased density and sometimes enlargement)
- ❑ Nausea
- ❑ Abdominal bloating
- ❑ Fluid retention in extremities
- ❑ Changes in the shape of the cornea of the eye (sometimes leading to contact lens intolerance)
- ❑ Headache (sometimes migraine)
- ❑ Dizziness
- ❑ Hair loss

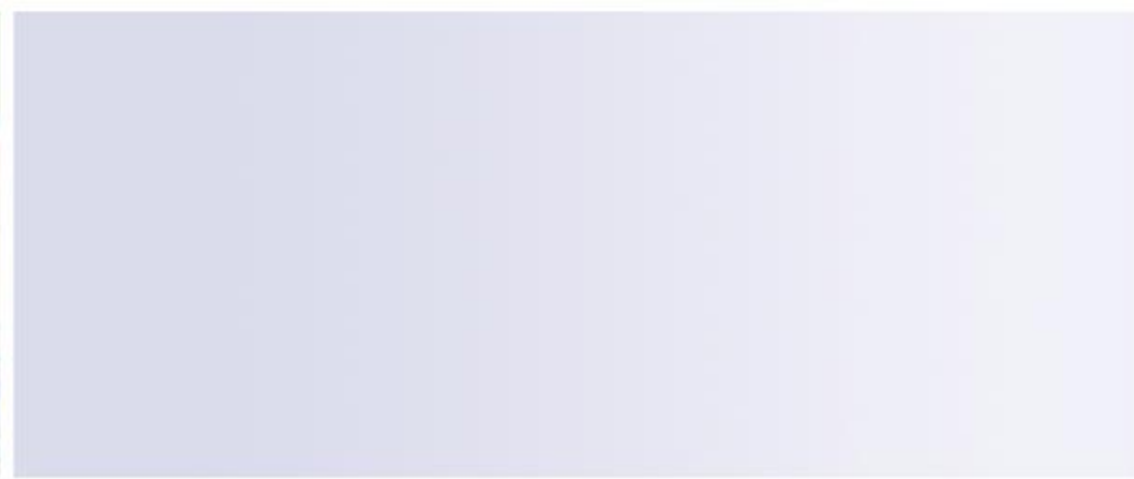


# Who Should NOT Consider Hormone Therapy?

Hormone therapy should not be used for women who may be pregnant or who have:

- ❑ Unusual vaginal or uterine bleeding
- ❑ Had certain cancers, including cancer of the breast or uterus
- ❑ Had a stroke or heart attack in the last year
- ❑ Had blood clots
- ❑ Had liver problems





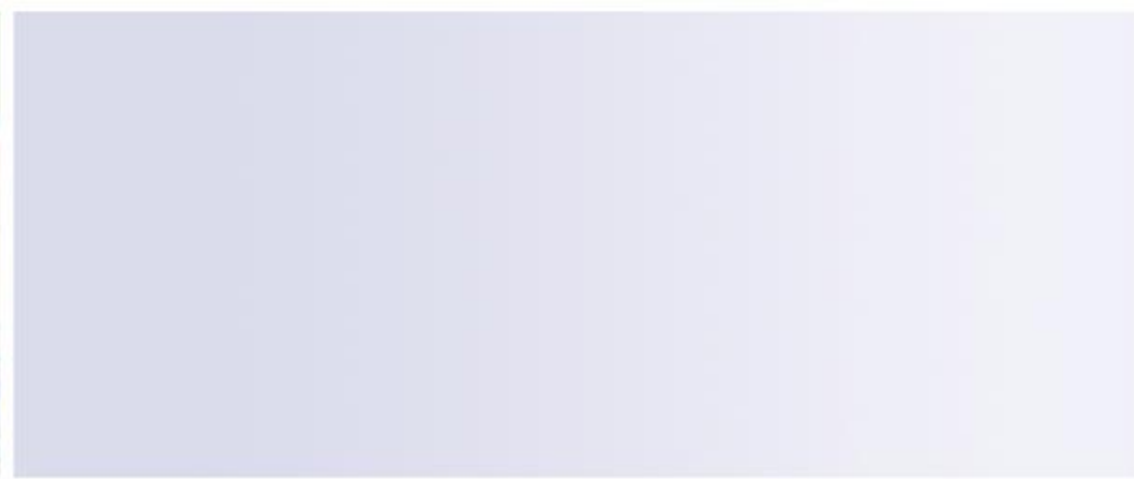
# Talk With Your Healthcare Professional



# Your Office Visit

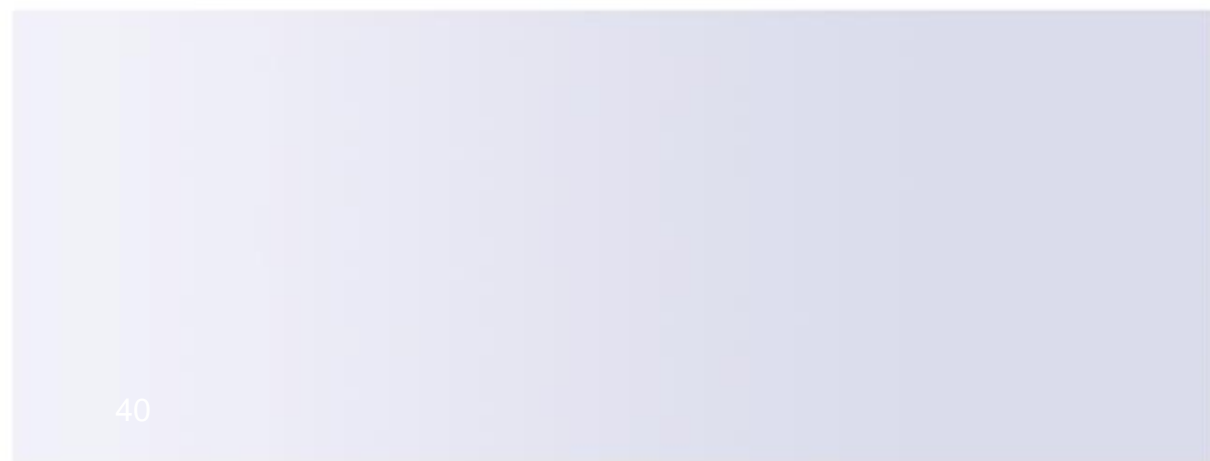
- ❑ **Before** you see your healthcare provider, do your research about menopause and hormone therapy
- ❑ **During** your visit, ask questions about:
  - ❑ All of the available options
  - ❑ Working on your lifestyle and health choices
  - ❑ Treatment benefits and risks
- ❑ Be sure to share all the information you can about:
  - ❑ Your medical history
  - ❑ Your family history
  - ❑ Any and all medications you're taking—including supplements, herbal treatments, and nonprescription drugs
- ❑ **After** your visit, call your healthcare professional about any side effects or changes in the way you feel
- ❑ See your healthcare professional regularly to evaluate your treatment approach. Stay informed. Stay empowered!





# Self-Evaluation

What You Should Know, What You Should Ask



# Evaluate Yourself

← **Not a Problem** **Severe Problem** →

Hot Flashes	1	2	3	4	5	6	7	8
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Quality of Sleep	1	2	3	4	5	6	7	8
Urinary Problems	1	2	3	4	5	6	7	8
Other Pain	1	2	3	4	5	6	7	8



# Summary

- ❑ Perimenopause and menopause are natural phases of your life
- ❑ The physical and psychological changes may have a real impact
- ❑ Work with your healthcare professional to understand your options and make the best choice for you and your lifestyle



# Additional Information

- ❑ The American College of Obstetricians and Gynecologists: [www.acog.org](http://www.acog.org)
- ❑ Food and Drug Administration, FDA Office of Women's Health, Menopause and Hormone Therapy Information:  
[www.FDA.gov/womens/menopause/default.htm](http://www.FDA.gov/womens/menopause/default.htm)
- ❑ National Institute on Aging, National Institutes of Health: [www.nia.nih.gov](http://www.nia.nih.gov)
- ❑ National Women's Health Resource Center: [www.healthywomen.org](http://www.healthywomen.org)
- ❑ The North American Menopause Society: [www.menopause.org](http://www.menopause.org)
- ❑ The Office on Women's Health, US Department of Health and Human Services: [www.4women.gov/owh](http://www.4women.gov/owh)
- ❑ The US government Web site, MedlinePlus: <http://medlineplus.gov>



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