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Oct 2006 "*Menopause & Symptomatic Therapy*" 707-000-06-010-H01

THIS MONTH
"Menopaus & Symptomatic Therapy"

CREDIT STATEMENTS FOR THIS YEAR WILL BE MAILED IN DECEMBER. DEADLINE FOR US TO RECEIVE QUIZZES & HAVE THEM APPEAR ON THIS CREDIT STATEMENT IS NOVEMBER 30, 2006.

CREDIT FOR QUIZZES RECEIVED IN DECEMBER 2006 WILL APPEAR ON CREDIT STATEMENTS THAT WILL BE MAILED IN JANUARY 2007.

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QUIZ DEADLINE FOR THIS YEAR IS NOVEMBER 30, 2006.

Menopause & Symptomatic Therapy is a topic that requires constant updating. The goal of this lesson is to provide information that can be conveniently shared with patients. This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-06-010-H01.
Pharmacists completing this lesson by October 31, 2009 may receive full credit.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe menopause & state the causes that trigger its occurrence.
2. Describe the physiological events that lead to menstruation.
3. State the major symptoms associated with menopause; list related disorders.
4. Discuss the various modes of estrogen delivery.
5. Describe the usefulness & risks involved in ERT.

BACKGROUND

The term menopause is derived from the Greek words ***menos,*** meaning month, and ***pausis***, which stands for cessation. Clinically, menopause may be defined as a physiological event that occurs after 12 consecutive months of absence of menstruation. The average age at menopause is 51 years, in spite of the facts that longevity in women has increased to 79.7 years and age at puberty has decreased. Thus postmenopausal years are becoming longer and may cause deterioration of quality of life and trigger certain disorders such as osteoporosis and cardiovascular disease. The age at which menopause commences is independent of race, physical characteristics, age at menarche or socioeconomic status. Tobacco smoking appears to hasten the onset of menopause by about 2 years, probably due to the adverse effect of nicotine on the ovaries or as a result of acceleration of hormonal metabolism. Hysterectomy may result in earlier onset of menopause, even in the presence of ovaries.

The time of transition to menopause is referred to as climacteric and occurs as a result of diminished estrogen secretion from the ovarian follicles. It has been estimated that a reproductive women has approximately 400,000 ovarian follicles in both ovaries. Only about 1,000 are released during the reproductive years. The remainders undergo atresia (blight or death of an ovarian follicle). Thus the increase in the age of a woman is accompanied by a gradual decrease in the ovarian follicle secretion. Ovarian weight decreases to about one - third of that before the commencement of menopause. In order for the follicles to mature, follicle stimulating hormone (FSH) must be present in significant concentrations. However, due to an increase in age, FSH levels begin to decline, and follicular maturation does not occur. In the absence of maturation, estradiol - 17 â production, ovulation, and progesterone secretion do not take place. It has been estimated that premenstrual concentration of estradiol is around 120 ng / L, while postmenopausal levels are approximately 16 – 18 ng/L. Such decline in estradiol level may lead to prolonging the menstrual intervals, absence of ovulation, and uterine bleeding. These symptoms are all signs of the approaching menopause. After menopause the main estrogen found in circulation is estrone, which is less potent than estradiol, and is usually found as a result of the conversion of the androgen, androstenedione. The conversion process occurs under the influence of the enzyme aromatase, which is abundant in fatty tissue and the liver. The level of this enzyme increases with age as more fatty tissue is accumulated in the body. Prior to menopause, the daily production of estrone and estradiol are 80-300 µg and 80-500 µg respectively. This compares to 40 µg of estrone and 6 µg of estradiol postmenopausally. The estradiol found in circulation after menopause is derived from the conversion of estrone to estradiol. Another hormone that is affected during climacteric is progesterone. During this time, progesterone level begins to diminish and eventually becomes minute after menopause.

PHYSIOLOGY OF MENSTRUATION

Only one egg is released from the ovary to the fallopian tube each month. In the days prior to ovulation, the uterine epithelium becomes thicker and more vascular. This thickening is necessary in order to provide support for the existence of the fertilized egg.

Menstruation occurs as a result of a complex interplay between the endocrine and target organs. The gonadotropin - releasing hormone secreted by the hypothalamus regulates the release of both luteinizing hormone (LH) and the follicle stimulating hormone (FSH) from the anterior portion of the pituitary gland. Both LH and

CE PRN® (ISSN 0199-5006) is owned and published by W-F Professional Associates, Inc.
400 Lake Cook Road, Suite 207, Deerfield, Illinois 60015.
William J. Feinberg, President
CE PRN® is published eleven times per year, monthly, January through November.
Subscription rate is $99.00 per year. Second-Class Postage paid at Deerfield, Illinois 60015
and at additional mailing offices.

POSTMASTER: Send all address changes to W-F Professional Associates, Inc., 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.
October 2006

FSH play an essential role in stimulating the secretion of hormones by the ovaries, and in maturation of the eggs within the follicles.

Menstruation occurs in cycles that begin approximately every 28 days. These cycles may differ from one month to the next and from one woman to another. They start at puberty and cease at menopause. Duration of the menstrual flow is 3 to 7 days. The average is 4 days. The sequence of events that lead to menstruation begins on the first day of the cycle. At that time the level of estrogen in circulation is very low. A gradual increase in estrogen production takes place beginning on that day. Such an increase is accompanied by an increase in the endometrium proliferation. The thickness of the endometrium begins at the end of the menstrual flow and reaches maximum thickness on day 14 of the cycle, in order to prepare the uterus for the embedding of the fertilized egg.

The low level of estrogen on the first day of the cycle, via the negative feedback, triggers the anterior portion of the pituitary gland to secrete FSH and LH. The FSH stimulates the ovaries to release estrogen, mainly estradiol, which eventually causes the maturation of the egg in the ovarian follicle by day 14 of the cycle. About 16 to 32 hours prior to ovulation, a surge of LH occurs. Under the influence of this LH surge, one of the mature ovarian follicles rupture and an egg is released into the fallopian tube, while the other mature follicles undergo degeneration (atresia). This event, ovulation, is usually accompanied by increases in vaginal secretions and body temperature. The gradual increase in the level of estrogen, especially estradiol, which begins on the first few days of the cycle, peaks at the time of the LH surge. The level of the progesterone begins to increase prior to the LH surge. On day 14 of the cycle, which is usually ovulation day, the level of LH and FSH reach their maximum concentrations. In the absence of pregnancy the high levels of LH and FSH will trigger the negative feedback of the hypothalamus - pituitary centers to stop producing LH and FSH. As a result of the absence of FSH, stimulation of the ovaries to produce estrogens becomes negligible and a decline in the level of estrogen will take place immediately following ovulation. By day 28, the level of estrogen is so low that it leaves the endometrium without hormonal support, and the lining begins to break down. The blood vessels become constricted, depriving the endometrium of blood supplies. As a result, the endometrium begins to shed, and a bloody menstrual discharge begins to flow. This signals day one of the new menstrual cycle. Discharge usually contains blood, disintegrated endometrial cells and gland secretions. It has a characteristic odor and normally does not coagulate, but formation of small clots may occur. The amount of discharge varies from one woman to another and from month to month, but the average is about 30 to 40 ml. Menstruation ceases during pregnancy, during lactation and permanently at menopause.

DISORDERS ASSOCIATED WITH MENSTRUATION

In general, patients may experience premenstrual and premenopausal psychological, behavioral and physical changes. Disorders such as dysmenorrhea, which is characterized by backache and abdominal cramps, and premenstrual syndrome (PMS) may occur premenstrually. PMS is associated with mood change, excitability, anxiety, depression, insomnia, fluid retention, breast tenderness and engorgement. It is estimated that 75% of patients experience one or more of the aforementioned symptoms. Up to 50% of women experience PMS. About 40% to 50% of women experience dysmenorrhea, in particular abdominal cramps and bloating.

SYMPTOMS OF MENOPAUSE

Symptoms of menopause in the climacteric period occur as a result of estrogen deficiency. Vasomotor symptoms such as hot flushes, genitourinary atrophy and osteoporosis are very common.

Hot Flashes are vasomotor symptoms experienced by 50% to 85% of women during the climacteric period. They are characterized by a feeling of warmth over the chest, neck, and facial area that may appear as red flushing. The patient complains of increased sweating especially at night. They may emerge prior to the last menstrual cycle experienced, but occur most frequently during the two years after the beginning of menopause and gradually diminish over time. The vast majority of individuals complain of experiencing these for longer than one year, but about 25% of the sufferers are affected for longer than 5 years. Their duration is about 4 minutes. Other vasomotor symptoms include: headache, dizziness, palpitation, nausea, vomiting, high sweats, irritability, and insomnia, which may lead to fatigue. Estrogen therapy may provide symptomatic relief. The patient may begin with a low oral dose of 0.3 - 0.45 mg of estrogen. Estrogen - progestin therapy may be attempted for women with an intact uterus. Transdermal estradiol may be used as an alternate. A recommended starting daily dose is 0.025 or 0.05 mg. The dose may be increased to 0.1 mg/day only if the symptoms persist.

Genitourinary Atrophy: As estrogen begins to decline, menopausal patients may experience symptoms associated with atrophy of the genitourinary tract. These changes may occur in the vulva, vagina, uterus, urethra and urinary bladder. The vagina becomes smaller, dry, thin, looses its ruga appearance (transverse folds) and becomes pale. About 10% to 40% of individuals experience genitourinary symptoms. Many women find such symptoms to be tolerable and do not seek medical advice.

The pH of a normal healthy vagina is acidic and ranges from 4.5 to 5.0. During menopause the vaginal pH may reach 6 to 8, and thus predisposes the menopausal patient to vaginal fungal or bacterial infections. In addition to atrophy in the vagina, atrophic changes may take place in both the urethra and urinary bladder. Such changes may lead to nonbacterial urethritis which is characterized by dysuria (painful urination), frequent and urgent urination and nocturia (frequent urination at night). Incontinence may be encountered by postmenopausal women.

Local (intravaginally) or systematic estrogen therapy may provide symptomatic relief of genitourinary atrophy. Daily application of intravaginal cream for 1 to 3 months, and then intermittently as needed, is recommended. Vaginal tablets containing 2 µg of estradiol may be used daily for two weeks then twice daily. Vaginal rings that slowly release 7.5 µg of estradiol daily for 90 days may be used.

Osteoporosis: Osteoporosis is a disease characterized by low bone mass and microarchitectural deterioration of bone tissue. This leads to bone fragility and increased risk of bone fracture. Bones are either cortical or cancellous (spongy, lattice-like). The cortical bones are dense and located in the outer layers of the skeleton, whereas the cancellous bones are situated in the interior portion. The long bones of the skeleton consist mostly of cortical bones except for their ends which are mainly cancellous. A continuous remodeling process in bones occurs as a result of a balance between osteoblasts, which helps in rebuilding of bony surfaces, and osteoclasts, which resorb bone.

Bone mass reaches its highest level at 30 to 35 years of age. After this age cortical bones begin to decline by up to 0.5% each year. At menopause, this decline in cortical bone mass accelerates to reach 2% to 3% yearly. This decrease occurs as a result of diminished concentration of estradiol. Cancellous bone loss begins during the third decade of life with yearly decrease of about 0.6 to 0.8% each year.

Osteoporosis is a major public health problem that affects over 11 million people in the US. Obviously, the incidence increases as patients become older. The frequency of fractures also increases with age. Over 1.5 million osteoporosis related fractures occur each year. Most of these are in the vertebrae, distal radius and hips. It has been estimated that 40% of Caucasian females over 50 years of age will suffer fractures of the spine, distal forearms or hip during their lifetime. Women who experience hip fractures have a 12% to 20% higher mortality rate. Annual cost in the U.S. of osteoporosis related fractures exceeds $14 billion.

To reduce future risk of developing osteoporosis, the patient should be advised to maximize the peak bone mass and prevent bone loss. The intake of adequate amounts of vitamin D, which assists in calcium regulation, is recommended. Daily requirements of vitamin D range from 200-600 IU. It is also important to ensure that the patient receives about 1,000 mg of calcium per day, whether this amount is through diet or in the form of a supplement.

ESTROGEN REPLACEMENT THERAPY

Quality of life, as well as mortality caused by estrogen and progestin deficiency, may improve following estrogen replacement therapy (ERT). This approach assists to prevent osteoporosis, genitourinary atrophy and vasomotor symptoms of menopause. The main objectives of ERT are to improve the quality of life and to prevent or reduce the risk of emergence of disorders associated with menopause. The rationale behind the use of ERT is to reestablish an adequate level of estrogen, thereby relieving the climacteric symptoms of menopause. It is estimated that as many as half the postmenopausal women in the USA use one or more forms of estrogen replacement products. The active drug includes: conjugated estrogen, estrogen substitute (i.e., diethylstilbestrol), synthetic estrogens (i.e., ethinyl estradiol) or micronized estradiol. The most widely used one is conjugated estrogen, which consists of estrone sulfate and multiple other equine estrogens. In addition to providing relief from climacteric symptoms, there is evidence to indicate that it can prevent osteoporosis and exert positive effects on calcium balance and bone density. It has been shown that women given ERT have experienced lesser incidence of bone fracture.

Dosing information must be thoroughly explained to the patient. For long-term therapy, ERT should be administered at the lowest effective dose. The patient must be evaluated every year to determine the need for continuation of medication. Prolonged ERT, along with the concurrent use of progestin for at least 10 to 14 days of each cycle, may be attempted in postmenopausal patients with an intact uterus. This tends to decrease the risk of development of endometrial hyperplasia and endometrial carcinoma. Estrogen is usually given alone for the first 15 days, and in combination of estrogen and progestin for the remainder of the month. Other regimens involve the continuous administration of estrogen along with low dose continuous progestin. Additionally, ERT may be used on a cyclic or continuous basis. A patient may follow a cyclic regimen consisting of three weeks of estrogen with progestin concurrently administered for the first or last 10 to 14 days of the three-week period. During the fourth and final week of the cycle, no medication is given. The dose of estradiol, as well as the frequency of administration and duration of use, varies from one individual to another depending on the medical problem for which the medication is taken or applied.

ADVERSE EFFECTS OF ERT

A potential adverse effect of ERT is the increased risk of endometrial cancer. The risk after 5 years of estrogen use is believed to increase by a factor of 3.5. This risk seems to rise with increasing duration and dosage of estrogen. The inclusion of progestin with estrogen has been shown to reduce the endometrium mitotic activity. The association of breast cancer with ERT has not been resolved. Some studies have shown that the use of estrogen in high doses and for prolonged period (longer than 10 years) has increased the risk of breast cancer. Other studies did not indicate this finding in patients who used ERT. There is no conclusive evidence to indicate that low doses of ERT in postmenopausal women contribute to an increase in the severity or incidence of thromboembolic disease, hypertension, atherosclerosis, myocardial infarction or stroke.

METHODS OF ADMINISTRATION

Estrogen occurs naturally or may be synthetically prepared. The oral route has been utilized for over 55 years. Today, a wide range of delivery systems are used allowing long term therapy to be designed for individual use. Estrogen may be administered orally, transdermally, intravaginally, intramuscularly or subcutaneously as implanted pellets. The most convenient routes are oral and transdermal.

Oral route: This provides adequate blood level of estrogen and effective relief of symptoms. It is convenient, easy to stop, relatively inexpensive, and there is a short half – life. The main disadvantage is that only about 10% of the dose reaches systemic circulation due to the fact that it undergoes conversion to inactive metabolites in the GI tract, and because of first pass metabolism in the liver. Hepatic effects on orally administered estrogen may cause increased risks of gallstone formation, hypertension, and hypertriglyceridemia.

The recommended average dose of conjugated estrogens is 0.3 to 1.25 mg daily; for esterified estrogens, the average dose is 0.625 to 1.25 mg daily; for estradiol, the average dose is 0.5 to 2 mg; and for estropipate the average dose is 0.75 to 6 mg. A combination of estradiol (5 mcg) and norethindrone (1 mg) in each tablet may be taken.

In case of a missed dose, the medication should be taken as soon as possible, unless it is almost time for the next dose. Instead, the missed dose should be skipped and the regular dosing schedule resumed.

Transdermal: Transdermal routes are available as patches or gels. Transdermal estrogen is absorbed directly from the skin, and enters the circulation in a regular continuous manner, thereby establishing estradiol – estrone ratios identical to that encountered by postmenopausal women. Advantages of this route include: (1) estrogen avoids the influence of the GI tract and does not undergo first pass hepatic metabolism. (2) This route appears to have no effect on clotting factors, and no hepatobiliary effects similar to those encountered following oral administration. The main side effect of transdermal patches is irritation at the application site. However, it appears that matrix patches cause less adverse skin reactions than the reservoir patches. The use of transdermal patches enhances patient compliance.

One type of skin patch contains 0.025 to 1 mg estradiol, and should be applied to the skin and worn for a week. After that, the patch is removed and a new one is applied. The patches are applied weekly for three weeks. In the fourth week, the physician may not recommend applying a new patch. At the end of the fourth week, a new cycle should be repeated.

Another type of patch contains 0.025 to 0.1 mg. The patch is applied to the skin and worn for 3 ½ days

(½ week) .Then it is removed and a new one is applied and worn for the rest of the week. The patches are applied twice a week for three weeks. During the fourth week, the physician may or may not recommend that a new patch be used. After the fourth week, the cycle is repeated. If the patient forgets to apply a patch on its due time, the patch should be applied as soon as possible, provided that it is not time for the next patch. In such a case, the missed patch should be skipped and a new schedule should be resumed.

The application of a hydroalcoholic transparent gel containing 0.6 mcg of estradiol results in rapid absorption through the skin, causing therapeutically effective blood levels. This dosage form, which is available in Europe, is applied to the lower abdomen or arms and shoulders, and is allowed to dry for 2 to 3 minutes. It tends to relieve menopausal symptoms without causing changes in liver protein production.

Crystalloid Implants: Estradiol implants (pellets) that contain 25 to 200 mcg of the hormone are implanted subcutaneously under local anesthetic. The drug is transported directly into the circulation, thereby avoiding first pass hepatic metabolism. The implanted pellet helps maintain adequate blood levels for 6 to 12 months, but may continue to release estrogen in small quantities for a longer time. Dose and its frequency are determined by weight of the patient and severity of the menopausal symptoms. Crystalloid implants possess the advantage of ensuring compliance, especially for forgetful patients. Frequent administration of these implants may lead to higher estrogen levels, especially since minimal metabolism occurs in the subcutaneous tissue. To prevent this from occurring, the implants may be administered once every 6 weeks and at a dose of 25 mcg. The drawback of this route is that minor surgery is required for insertion and removal, enhancing the risk of infection.

Vaginal routes: Vaginal estrogen therapy is usually intended to achieve local effects rather than systemic. Menopause can result in atrophic vaginitis and vulvar atrophy. Local estrogen therapy is effective in relieving these symptoms. Vaginal preparations utilized in estrogen delivery include cream, inserts (rings) and suppositories.

Creams are applied with an applicator with marks indicating the amount to be inserted. For treating vulvar atrophy and atrophic vaginitis in postmenopausal patients, one-half to two grams of conjugated estrogen cream containing 0.3 to 1.25 mg are inserted into the vagina once a day or as directed by the physician. The cream should be used for only three weeks of each month. For estradiol vaginal cream, the dose is 200 to 400 mcg (2 to 4 grams of cream) once a day for one to two weeks, decreasing the dose by ½ over two to four weeks. After four weeks, the dose and its frequency may be reduced.

The drawback of vaginal creams is the difficulty of measuring and administering the cream for elderly patients, especially those with poor sight. Additionally, the administration is messy and unpleasant, leading to poor compliance.

Inserts are sustained – release delivery systems made of a biologically inert-liquid polymer matrix, combined with pure crystalline estrogen. The insert or ring is about 55 millimeters in diameter, and is held in place during daily activities by the vaginal wall. The insert contains 2 mg, releasing 7.5 mcg every twenty- four hours continuously. The insert should be replaced every three months.

Vaginal suppositories of estrogen, each containing 250 to 500 mcg, are inserted once daily or as directed by the physician.

MISCELLANEOUS THERAPY

Phytoestrogens: Phytoestrogens are derived from plants, but structurally and functionally resemble estrogen synthesized by the body. These chemicals are widely distributed in oil seeds, vegetables and soy beans. There are a number of herbal products that have been utilized for PMS and menopausal symptoms. However, recent research to determine the active ingredients, mechanism of action and potential clinical usefulness provided varying degrees of benefits of phytoestrogens for symptomatic relief of menopause. Safety studies for herbal products during pregnancy and lactation are inconclusive.

Soybeans and Isoflavones: The main active constituents in soybeans are isoflavones which possess weak estrogenic activity ranging from 500 to 15,000 times less than that of estradiol. Reports indicate that soybeans may provide relief from menopausal hot flashes.

Dong Quai: Dong quai has been used for premenopausal or menopausal hot flashes as well as for PMS. Even though its efficiency for such therapy is questionable, its safety profile appears to be good.

Black cohosh: Black cohosh is an herb native to Eastern North America. Native Americans used black cohosh for treating amenorrhea and menopause. Currently, black cohosh is used in the treatment of hot flashes,

menopausal anxiety and depression. Extracts from the drug have been used in younger women suffering from hormonal deficits following ovariectomy or hysterectomy as well as juvenile menstrual disorders.

Licorice root: Several isoflavones have been isolated from licorice root and illustrate antioxidant activity. Of these, glabridin is the main constituent (11%) of an alcohol extract. Its lipophilicity and structure are similar to natural estrogens. It has been shown that glabridin and its derivatives function as an estrogen agonist. At the present time there is no documentation to show the potential effectiveness of licorice root as an alternative to ERT.

CONCLUSION

This concludes our review of "Menopause & Symptomatic Therapy." As always, our goal is to present information that can be conveniently shared with patients.

Presently we are working on the list of topics for 2007. Any suggestions? Send them to us.

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Fill in the information below, answer questions and return **Quiz Only** for certification of participation to:
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LESSON EVALUATION

Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Describe menopause & state the causes that trigger its occurrence	Yes	No
Describe the physiological events that lead to menstruation	Yes	No
State the major symptoms associated with menopause	Yes	No
List related disorders	Yes	No
Discuss the various modes of estrogen delivery	Yes	No
Describe the usefulness & risks involved in ERT	Yes	No

2. Was the program independent & non-commercial? Yes No

	Poor			Average			Excellent
3. Relevance of topic to your practice	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____

5. What did you like least about this lesson?_____

(WATCH OUR WEBSITE FOR RESULTS OF PARTICIPANT EVALUATIONS)

Quiz—Please Select the Most Correct Answer

1. Which of these is not used in ERT?
   A. Conjugated estrogen
   B. Diethylstilbestrol
   C. Micronized estradiol
   D. Testosterone

2. ERT increases the risk for endometrial cancer.
   A. True
   B. False

3. The level of estrogen on day one of the cycle is:
   A. Low
   B. At its peak
   C. On the decline
   D. Unchanged

4. Which of these is not a symptom of menopause?
   A. Hot flashes
   B. Urticaria
   C. Genitourinary atrophy
   D. Osteoporosis

5. There is no relationship between osteoporosis & bone fracture.
   A. True
   B. False

6. The average age of women at menopause is:
   A. 44
   B. 51
   C. 60
   D. 56

7. Concurrent use of estrogen & progestin tends to increase the risk of development of endometrial cancer.
   A. True
   B. False

8. Climacteric changes occur as a result of:
   A. Change in life style
   B. Physical characteristics of patient
   C. Tobacco smoking
   D. Diminished estrogen secretion

9. The transdermal route is available only as a cream.
   A. True
   B. False

10. Phytoestrogens are safe during pregnancy & lactation.
    A. True
    B. False

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