Put moderate to severe hot flashes due to menopause in their place with Duavee





IMPORTANT SAFETY INFORMATION AND INDICATIONS

INDICATIONS

Duavee is used after menopause for women with a uterus to reduce moderate to severe hot flashes and to help reduce the chances of developing osteoporosis (thin, weak bones).

If you use Duavee only to prevent osteoporosis due to menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you.

Duavee should be taken for the shortest time possible and only for as long as treatment is needed. You and your healthcare provider should talk regularly about whether you still need treatment with Duavee.

IMPORTANT SAFETY INFORMATION

Do not take progestins, additional estrogens, or additional estrogen agonists/ antagonists while taking Duavee[®] (conjugated estrogens/bazedoxifene).

Using estrogen alone may increase your chance of getting cancer of the uterus. Report any unusual vaginal bleeding right away while taking Duavee. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus. A healthcare provider should check unusual vaginal bleeding to find the cause.

Please see additional Important Safety Information throughout and click for <u>full Prescribing Information</u>, including BOXED WARNING and Patient Information.



May 2023

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What is menopause?

Menopause is a completely normal, natural stage in a woman's life. Every woman experiences it; however, not all women experience menopause in the same way.

Usually in a woman's 40s, periods become more unpredictable and less frequent. Estrogen levels drop, causing changes in the body, which may include hot flashes and bone loss.

Hot flashes can be described as feelings of warmth in the face, neck, and chest; a sudden strong feeling of heat; or a sudden onset of sweating. Some people may have severe hot flashes, and others may have no symptoms at all.

You're not alone, many of us have been there. Hot flashes can be unpredictable, which can be frustrating.



IMPORTANT SAFETY INFORMATION

Do not use estrogens to prevent heart disease, heart attacks, strokes, or dementia.

(continued)

Estrogen alone may increase the chance of getting blood clots or strokes.

Using estrogen alone may increase the chance of getting dementia, based on a study of women 65 years of age or older.

The risks listed on this and the previous pages are based on a study of an estrogen-alone oral product. Since other products and doses have not been studied in the same way, it is not known how the use of Duavee will affect your chances of getting these conditions.

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What is Duavee?



Duavee is the first and only pairing of its kind and is an estrogen-based therapy. It combines conjugated estrogens with bazedoxifene.

Estrogens help relieve hot flashes due to menopause. But for postmenopausal women with a uterus, taking estrogens alone increases the chance that the uterine lining will thicken. Duavee contains bazedoxifene, a selective estrogen receptor modulator, to help reduce the risk of overgrowth of the lining of the uterus (known as endometrial hyperplasia).

Duavee should be taken for the shortest time possible and only for as long as treatment is needed. You should talk to your doctor regularly to see if treatment is still needed.

Duavee treats moderate to severe prevents postmenopausal HOT FLASHES BONE LOSS due to menopause

INFORMATION (continued)

IMPORTANT SAFETY Estrogens should be used at the lowest dose possible, only for as long as needed. You and your healthcare provider should talk regularly about whether you still need treatment with Duavee.

> Do not use Duavee if you: have or had blood clots; are allergic to estrogens or bazedoxifene, the active ingredients of Duavee; have unusual vaginal bleeding; have or had certain cancers (e.g., uterine or breast), liver problems, or bleeding disorders; or are pregnant.

If you take thyroid medication, consult your healthcare provider, as use of estrogens may change the amount needed.

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How do I take Duavee?

Take one Duavee tablet orally every day. You can take Duavee at any time of the day, with or without food. If you take supplemental calcium and/or vitamin D, it may be taken at the same time as Duavee.

If you miss a dose of Duavee, take it as soon as you remember. However, if it is almost time to take your next dose of Duavee, skip the dose you missed and only take your next scheduled dose. **Do not** take 2 doses of Duavee at the same time.

How to store Duavee

Duavee should be stored at room temperature, 68 °F to 77 °F (20 °C to 25 °C). Keep Duavee in the blister packaging it came in until you are ready to take it to protect the tablet from moisture. It is not recommended to place Duavee in pillboxes or pill organizers. After opening the foil pouch the Duavee blister packs came in, Duavee must be used within 60 days.

IMPORTANT SAFETY Serious side effects include blood clots, stroke, heart attack, cancer of the lining of the uterus, breast cancer, cancer **INFORMATION** of the ovary, dementia, gallbladder problems, loss of vision, high blood pressure, increased fats in your blood, liver (continued) problems, thyroid problems, fluid retention, low calcium, swelling of your mouth or tongue, worsening of other medical problems such as asthma, diabetes, epilepsy, migraines, a genetic problem called porphyria, lupus and liver problems.

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Are there any side effects of Duavee?

As with any medication, you may experience side effects when taking Duavee. Before taking Duavee, it is important to share your complete health history with your doctor. You and your doctor can determine if Duavee is right for you.

Serious side • Gallbladder problems Blood clots Low calcium effects of Stroke Loss of vision or tongue Duavee include: Heart attack High blood pressure Increased fats in Cancer of the lining of the uterus vour blood Breast cancer • Liver problems • Cancer of the ovary Thyroid problems Fluid retention Dementia Less serious, but • Muscle spasms Upset stomach Dizziness common side effects Nausea • Abdominal pain Neck pain of Duavee include: • Diarrhea Throat pain

- Swelling of your mouth
- Worsening of other medical problems such as asthma, diabetes, epilepsy, migraines, a genetic problem called porphyria, lupus and liver problems



These are not all the possible side effects of Duavee. For more information, see Important Safety Information and speak with your doctor.

IMPORTANT SAFETY Call your healthcare provider right away if you have any of the following warning signs, or any other unusual symptoms **INFORMATION** that concern you: new breast lumps, unusual vaginal bleeding, changes in vision or speech, sudden new severe (continued) headaches, severe pains in your chest or legs with or without shortness of breath, weakness and fatigue. Less serious, but common side effects include: muscle spasms, nausea, diarrhea, upset stomach, abdominal pain, throat pain, dizziness, neck pain. You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit http://www.fda.gov/MedWatch or call 1-800-FDA-1088. Please see additional Important Safety Information throughout, Indications on page 1, and Previous full Prescribing Information, including BOXED WARNING and Patient Information.