The recommended dosage of BRISDELLE for the treatment of moderate to severe VMS is 7.5 mg/day.

**2.1 Dosage Information**

The dosage should be individualized for each patient based on their response and tolerability. For patients who have not responded to a 7.5 mg dose, an increase to 15 mg/day may be considered. However, if a 15 mg dose does not result in adequate symptom improvement, treatment with BRISDELLE should be discontinued. The maximum recommended daily dose is 15 mg.

**5.11 Potential for Cognitive and Motor Impairment**

BRISDELLE contains paroxetine, which has been associated with changes in cognitive and motor performance in clinical studies. Patients should be warned about the potential for cognitive and motor impairment, especially during the first few weeks of treatment or when the dose is increased. It is recommended to advise families and caregivers of the need for close observation and communication with the prescriber.

**11.2 Special Populations**

The safety and effectiveness of BRISDELLE have not been established in patients with renal impairment, dialysis patients, or patients with hepatic impairment. The use of BRISDELLE in these populations should be carefully considered based on the severity of the condition and the benefit-risk ratio.

**11.3 Other Drugs**

BRISDELLE should be used with caution in patients concurrently taking other drugs that may have a similar mechanism of action or interfere with the metabolism of paroxetine. This includes other SSRIs, SNRIs, and nortriptyline. The concomitant use of BRISDELLE with tryptophan is not recommended.

**13.4 Effects of Other Drugs on Paroxetine**

Specific drug interactions with paroxetine are listed in Table 3. When concomitantly used, the effects of other drugs on paroxetine may differ from those observed in the clinical trials of a drug cannot directly be compared to rates in the clinical trials of paroxetine. The clinical significance of these interactions should be evaluated on an individual basis.

**13.4.1 Effects of Paroxetine on Other Drugs**

Table 4 lists the effects of paroxetine on other drugs. When concomitantly used, the effects of paroxetine on other drugs may differ from those observed in the clinical trials of a drug; the clinical significance of these interactions should be evaluated on an individual basis.

**13.4.2 Potentially Important Drug Interactions**

Specific drug interactions are presented in Table 5. When concomitantly used, the effects of other drugs on paroxetine may differ from those observed in the clinical trials of a drug. The clinical significance of these interactions should be evaluated on an individual basis.
3. Known Foods. Women who take BRISDELLE may have a higher risk of getting bladder infections. Inform your healthcare provider if you have had in the past:
   • gloating increased energy
   • mouth sores
   • mood changes
   • nausea
   • unusual bleeding
   • urinating more than usually
   • tasting like metal
   • uncommon tiredness
   • weight gain
   • yellowing of skin or eyes

4. Balance or coordination

10. Pregnancy. Women who take BRISDELLE may get an increased sense of fatigue, nausea, dizziness, vomiting or changes in breast size while they are pregnant. Inform your healthcare provider if you are pregnant or think you may be pregnant.

What is BRISDELLE?

BRISDELLE is a prescription medicine used to reduce moderate to severe hot flashes in women who have already gone through menopause. BRISDELLE is a selective estrogen receptor modulator (SERM). It is not a hormone. The way BRISDELLE works is different from the way hormones such as conjugated equine estrogens (Premarin), diethylstilbestrol (DES), tamoxifen (Nolvadex) or raloxifene (Evista) work in the body for the body.

BRISDELLE is not used for treating postmenopausal osteoporosis.

Do not use BRISDELLE if you:
   • are allergic to any of the ingredients in BRISDELLE.
   • are pregnant or think you may be pregnant.
   • are breast feeding.
   • have a history of breast cancer.
   • have a history of stroke or heart attack.
   • have a history of blood clots in your legs.
   • have a history of abnormal enlargement of the breast.
   • have ever had cancer of the breast.
   • have problems with blood clotting.
   • have any emotional, psychiatric, or psychiatric disorder.
   • have had prior suicide attempts.
   • have a history of an unusual bleeding problem.
   • have had a liver disorder.
   • have a history of diabetes.
   • have a history of uterine cancer.
   • have a history of ovarian cancer.
   • have a history of uterine fibroids.
   • have a history of endometrial cancer.
   • have a history of breast cancer.
   • have a history of a seizure disorder.
   • have a history of blood clots in your lungs.
   • have a history of angina.
   • have a history of abnormal bleeding.
   • have a history of depression.
   • have a history of migraines.
   • have a history of jaundice.
   • have a history of osteoporosis.
   • have a history of alcoholism.
   • have a history of hypothyroidism.
   • have a history of heart failure.
   • have a history of severe anemia.
   • have a history of blood clots in your liver.
   • have a history of blackouts.

Tell your healthcare provider about the medicines you take. Include prescription and nonprescription medicines, vitamins, and herbal supplements. BRISDELLE and some medicines can interact with each other and may not work as well as you may expect or may cause side effects. Tell your healthcare provider if you are taking or think you may be taking:

BRISDELLE may cause serious side effects

Call your healthcare provider right away if you have any of the following symptoms, or go to the nearest emergency room:

1. Accidental thoughts or actions: BRISDELLE, and related antipsychotic medicines, may increase suicidal thoughts or actions within the first 1-2 months of treatment.

   BRISDELLE is associated with increased risk of suicidal thoughts or actions in elderly women. For this reason, you should be closely watched at the start of treatment.

2. Heart problems. Your healthcare provider should do a physical examination and check your heart before you start BRISDELLE. Also, your healthcare provider should check your heart every 6 months while you are using BRISDELLE. Check with your healthcare provider right away if you have any of the following symptoms:

   • chest pain or discomfort.
   • fast, slow, or irregular heartbeat.
   • shortness of breath.
   • swelling of your legs or feet.
   • swelling.
   • feeling light-headed or faint.
   • weakness.
   • cold sweats.
   • skin, lips, or nail beds that are bluish.
   • swelling of your ankles or feet.
   • coughing.
   • chest pain.
   • chest tightness.
   • trouble eating or swallowing.
   • unusual tiredness.
   • rapid or uneven heartbeat.
   • pain or pressure in your chest.
   • cold, clammy, pale skin.
   • lightheadedness.
   • trouble breathing.
   • unusual bleeding or bruising.
   • blood clots.
   • nausea.
   • vomiting.
   • constipation.
   • diarrhea.
   • black, tarry, bloody, or柏ish stools.
   • urine that is darker than normal.
   • unusual weakness.
   • unusual weight gain.
   • blood in your urine or stool.
   • dark urine.
   • decreased or no urine.
   • dizziness.

3. Skin problems. Women who take BRISDELLE may have a higher risk of getting bladder infections. Inform your healthcare provider if you have had any of the following in the past:

   • bladder pain.
   • fever.
   • increased urination.
   • new blood in your urine.
   • new eye problems.
   • not passing enough urine.
   • pus in your urine.
   • red or sore genital area.
   • severe itching.
   • tenderness of your bladder.
   • unusual bleeding.
   • unusual pain when you urinate.
   • unusual smell.
   • unusual urgency.
   • unusual swelling.
   • unusual tingling.
   • unusual urge to urinate.
   • unusual weight gain.
   • urinary tract infection.
   • urgency.
   • vaginal bleeding.
   • vaginal itching.
   • vaginal irritation.
   • vaginal itching or irritation that is unusual.
   • vaginal pain.
   • vaginal redness.
   • vaginal soreness.
   • vaginal sores.
   • vaginal secretions.
   • vaginal tingling.
   • vaginal dryness.
   • vaginal itching.
   • vaginal irritation.
   • vaginal redness.
   • vaginal soreness.
   • vaginal bleeding.
   • vaginal discharge.
   • vaginal discharge that is unusual.
   • vaginal itching.
   • vaginal irritation.
   • vaginal redness.
   • vaginal soreness.
   • vaginal secretions.
   • vaginal tingling.
   • vaginal dryness.
   • vaginal itching.
   • vaginal irritation.
   • vaginal redness.
   • vaginal soreness.
   • vaginal secretions.
   • vaginal tingling.
   • vaginal discharge.