BRISDELLE® (paroxetine)

LENGTH OF AUTHORIZATION: UP TO 12 MONTHS

APPROVAL INDICATIONS FOR INITIAL THERAPY:

1. Must be ≥18 years of age.
2. Must have a moderate to severe vasomotor symptoms associated with menopause
3. Must have a trial and failure of preferred agents with the same indication (e.g. Premarin, estradiol etc.) or documented contraindication to preferred agents, such as current, past or suspected breast cancer, estrogen-dependent neoplasia, genital bleeding, endometrial hyperplasia, thromboembolic disease, liver dysfunction, hypersensitivity to menopausal hormone therapy, or porphyria cutanea tarda.

DOSING & ADMINISTRATION:

- The recommended dosage of BRISDELLE is 7.5mg once daily at bedtime.
- Dosage Form: 7.5mg capsule