Brisdelle® (paroxetine) 7.5 mg

Fax to 1-877-540-6497
Noven Therapeutics, LLC. Women's Health

Sample Request Form

Reference# WEB

MD DO PA NP Other

Practitioner's Last Name **First Name** (required) **Professional Designation**

State License Number (required) **Expiration Date** (required)

Office Address (required-PO boxes are not accepted) **City** (required) **State** (required) **Zip** (required)

Phone Number Fax Number Email

Brisdelle® (paroxetine) Samples

Please check the box for sample dose requested and literature.

☐ 10 packs of Brisdelle 7.5-mg/day (7 capsules per pack)

☐ 10 Brisdelle CoPay Cards

☐ 10 Brisdelle Patient Brochures

NOTE

While supplies last. Only 1 form can be submitted per month. This form must be filled out completely before your sample request can be processed.

You should expect samples to arrive within 2 weeks from the date your fax request is received. If you have any questions regarding your request, please call 1-877-540-6498 (M-F 8am-5pm EST).

Practitioner Certification

I, a licensed practitioner, certify that all the information on this form is correct and that I am licensed with the appropriate state authorities and eligible under state law to request, receive, prescribe, and dispense the above samples. I have requested the packaged quantities shown on this document for the product indicated. I understand and agree that the samples are subject to the requirements of the Prescription Drug Marketing Act and cannot be sold, traded, bartered, billed, returned for credit, or utilized to seek reimbursement.

Date: / /

Practitioner's Signature (Request cannot be fulfilled unless this form is signed and dated in ink. Must be original, no signature stamps accepted.)

Brisdelle® (paroxetine) Indication

BRISDELLE® (paroxetine) is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

BRISDELLE is not indicated for the treatment of any psychiatric condition. BRISDELLE contains a lower dose of paroxetine than that used for psychiatric conditions. The safety and efficacy of this lower dose of paroxetine in BRISDELLE have not been established for any psychiatric condition. Patients who require paroxetine for treatment of a psychiatric condition should discontinue BRISDELLE and initiate a paroxetine-containing medication that is indicated for such use.

Brisdelle® (paroxetine) Important Safety Information

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants, including selective serotonin reuptake inhibitors (SSRIs), have been shown to increase the risk of suicidal thoughts and behavior in pediatric and young adult patients when used to treat major depressive disorder and other psychiatric disorders. Because BRISDELLE is an SSRI, monitor patients closely for worsening and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

Important Safety Information continued on next page.

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Brisdelle® (paroxetine) Important Safety Information (continued)

CONTRAINDICATIONS:

- Concurrent use with monoamine oxidase inhibitors (MAOIs)
  - or use within 14 days of MAOI use
  - or starting BRISDELLE in a patient who is being treated with linezolid
  - or intravenous methylene blue

  Because of an increased risk of serotonin syndrome.
- Concomitant use with thioridazine or pimozide due to their increased plasma concentrations and because of the potential of QTc prolongation.
- Hypersensitivity to any ingredient in BRISDELLE.
- Pregnancy because BRISDELLE may cause fetal harm.

WARNINGS AND PRECAUTIONS:

- *Suicidality:* **All patients being treated with BRISDELLE should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of treatment.**
- *Serotonin Syndrome:* Serotonin syndrome, which is potentially life-threatening, has been reported with concomitant use of serotonergic drugs, and with drugs that impair metabolism of serotonin (in particular, MAOIs). Monitor patients for the emergence of serotonin syndrome. Discontinue BRISDELLE and any concomitant serotonergic agents and initiate supportive treatment.
- *Tamoxifen:* Efficacy of tamoxifen may be reduced when administered concomitantly with BRISDELLE.
- *Abnormal Bleeding:* SSRIs, including BRISDELLE, may increase the risk of bleeding events. Caution patients about the risk of bleeding associated with the concomitant use of BRISDELLE and non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation.
- *Angle Closure Glaucoma:* Angle-closure glaucoma has occurred in patients treated with antidepressants with untreated anatomically narrow angles
- *Hyponatremia:* may occur as a result of treatment with SSRIs, including BRISDELLE. Elderly patients may be at greater risk and in many cases it can occur in association with syndrome of inappropriate antidiuretic hormone secretion (SIADH). Consider discontinuation of BRISDELLE in patients with symptomatic hyponatremia and institute appropriate medical intervention.
- *Bone fracture:* Epidemiological studies have reported an association between SSRI treatment and fractures.
- *Activation of Mania/Hypomania:* Screen for bipolar disorder and monitor for mania/hypomania.
- *Seizures:* Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold.
- *Akathisia:* Can occur, most likely in the first few weeks of treatment. Discontinue treatment with BRISDELLE if akathisia occurs.
- *Cognitive and Motor Impairment:* May cause impairment; patients should not operate machinery or motor vehicles until certain that BRISDELLE does not affect them adversely.

ADVERSE REACTIONS:

The most common adverse reactions (≥ 2%) reported in clinical trials were: headache, fatigue, and nausea and vomiting. Of these, nausea occurred primarily within the first 4 weeks of treatment and fatigue occurred primarily within the first week of treatment, and decreased in frequency with continued therapy.

To report SUSPECTED ADVERSE REACTIONS, contact Noven Therapeutics, LLC at 1-800-455-8070 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

DRUG INTERACTIONS:

Paroxetine is a strong CYP2D6 inhibitor. Co-administration of BRISDELLE can alter concentrations of other drugs that are metabolized by CYP2D6. Use caution if co-administering BRISDELLE with other drugs that are metabolized by CYP2D6.

These are not all the possible side effects of BRISDELLE. **Please click here for the full Prescribing Information including Boxed WARNING and patient Medication Guide.**

NOVEN
THERAPEUTICS, LLC