

MEDICATION GUIDE

BRISDELLE® (bris-del)

(Paroxetine)

Capsules

Read the Medication Guide that comes with BRISDELLE before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about. BRISDELLE contains a lower dose of paroxetine, a medicine also used to treat a number of psychiatric disorders. The lower dose of paroxetine in BRISDELLE has not been studied in any psychiatric conditions and BRISDELLE is not approved for any psychiatric uses.

What is the most important information I should know about BRISDELLE?

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. Suicidal thoughts or actions:

- **BRISDELLE, and related antidepressant medicines, may increase suicidal thoughts or actions within the first few months of treatment.**
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when BRISDELLE is started.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood.

2. Serotonin Syndrome. This condition can be life-threatening and may include:

- agitation (nervousness), hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (small movements of the muscles that you cannot control)
- racing heartbeat, high or low blood pressure

- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity
- dizziness
- flushing
- tremors
- seizures

3. Reduced effectiveness of tamoxifen. Tamoxifen (a medicine used to treat breast cancer) may not work as well if it is taken while you take BRISDELLE. If you are taking tamoxifen, tell your healthcare provider before starting BRISDELLE.

4. Abnormal bleeding. BRISDELLE may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin or non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen, naproxen, or aspirin.

5. Visual problems.

- Eye pain
- Changes in vision
- Swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

6. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this condition. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems.

7. Bone Fractures. Women who take BRISDELLE may have a higher risk of bone fractures. Contact your healthcare provider if you have pain in a bone.

8. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual.

9. Seizures or convulsions.

10. Restlessness. Women who take BRISDELLE may feel an inner restlessness, agitation (nervousness), or be unable to sit still or stand still especially when they start taking BRISDELLE. Call your healthcare provider if this happens to you.

11. Driving. BRISDELLE may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other potentially dangerous activities until you know how BRISDELLE affects you.

What is BRISDELLE?

BRISDELLE is a prescription medicine used to reduce moderate to severe hot flashes associated with menopause. BRISDELLE is a selective serotonin reuptake inhibitor (SSRI). It is not a hormone. The way BRISDELLE treats hot flashes associated with menopause is not known. BRISDELLE does not prevent or treat osteoporosis or dryness, itching or burning in and around the vagina.

BRISDELLE is not for psychiatric problems such as depression, obsessive compulsive disorder, panic disorder, generalized anxiety disorder, social anxiety disorder, and post-traumatic stress disorder.

BRISDELLE is not for use in children.

Talk to your healthcare provider if you do not think that your hot flashes are getting better while taking BRISDELLE.

Who should not take BRISDELLE?

Do not take BRISDELLE if you:

- **take a Monoamine Oxidase Inhibitor (MAOI).** Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
 - Do not take an MAOI within 14 days of stopping BRISDELLE unless directed to do so by your healthcare provider.
 - Do not start BRISDELLE if you stopped taking an MAOI in the last 14 days unless directed to do so by your healthcare provider.
 - **People who take BRISDELLE close in time to an MAOI may have serious or life-threatening side effects. Get medical help right away if you have any of these symptoms:**
 - high fever
 - uncontrolled muscle spasms
 - stiff muscles
 - rapid changes in heart rate or blood pressure
 - confusion
 - loss of consciousness (pass out)
- **take thioridazine.** Do not take thioridazine together with BRISDELLE because this can cause serious heart rhythm problems or sudden death.
- **take the antipsychotic medicine pimozide.** Do not take pimozide together with BRISDELLE because this can cause serious heart problems.
- **are allergic to paroxetine or any of the ingredients in BRISDELLE. See the end of this Medication Guide for a complete list of ingredients in BRISDELLE.**
- **are pregnant.** BRISDELLE is not for pregnant women. Paroxetine, the active ingredient in BRISDELLE, can harm your unborn baby. Risks to your unborn baby include an increased risk of birth defects, particularly heart defects. Your baby may also have certain other serious symptoms shortly after birth.

What should I tell my healthcare provider before taking BRISDELLE?

Before starting BRISDELLE, tell your healthcare provider if you:

- have liver problems

- have kidney problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have or had bleeding problems
- have glaucoma (high pressure in the eye)
- have any other medical conditions
- **are breastfeeding or plan to breastfeed.** BRISDELLE passes into breast milk. Talk to your healthcare provider before taking BRISDELLE if you are breast-feeding.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BRISDELLE and some medicines may interact with each other, may not work as well, or may cause serious side effects when taken together.

If you take BRISDELLE, you should not take any other medicines that contain paroxetine, including Paxil, Paxil CR and Pexeva.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including MAOIs, SSRIs, tricyclics, lithium, buspirone, or antipsychotics
- tramadol, fentanyl or over-the-counter supplements such as tryptophan or St. John's Wort
- thioridazine
- pimozide
- tamoxifen
- atomoxetine
- cimetidine
- digoxin
- theophylline
- medicines to treat irregular heart rate (like propafenone, flecainide, and encainide)
- medicines used to treat schizophrenia
- certain medicines used to treat HIV infection
- the blood thinner warfarin
- nonsteroidal anti-inflammatory drugs (NSAIDs) (like ibuprofen, naproxen, or aspirin)
- certain medicines used to treat seizures (like phenobarbital and phenytoin)
- other drugs containing paroxetine, the medicine in BRISDELLE.

Ask your healthcare provider if you are not sure if you are taking any of these medications.

Your healthcare provider or pharmacist can tell you if it is safe to take BRISDELLE with your other medicines. Do not start or stop any medicine while taking BRISDELLE without talking to your healthcare provider first.

How should I take BRISDELLE?

- Take BRISDELLE exactly as your healthcare provider tells you to take it.
- Take BRISDELLE 1 time each day at bedtime.
- BRISDELLE may be taken with or without food.
- If you miss a dose of BRISDELLE, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of BRISDELLE at the same time.
- If you take too much BRISDELLE, call your healthcare provider or poison control center right away, or go to the nearest emergency room right away.

What should I avoid while taking BRISDELLE?

- BRISDELLE can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how BRISDELLE affects you.

What are the possible side effects of BRISDELLE?

BRISDELLE may cause serious side effects, including:

- See “What is the most important information I should know about BRISDELLE?”

The most common side effects of BRISDELLE include:

- headache
- tiredness
- nausea and vomiting

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of BRISDELLE. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BRISDELLE?

- Store BRISDELLE at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep BRISDELLE out of the light.
- Keep BRISDELLE dry.
- **Keep BRISDELLE and all medicines out of the reach of children.**

General information about the safe and effective use of BRISDELLE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BRISDELLE for a condition for which it was not prescribed. Do not give BRISDELLE to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about BRISDELLE. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about BRISDELLE that is written for healthcare professionals.

For more information about BRISDELLE call 1-800-455-8070 or go to www.BRISDELLE.com.

What are the ingredients in BRISDELLE?

Active ingredient: paroxetine

Inactive ingredients: dibasic calcium phosphate, sodium starch glycolate, magnesium stearate, gelatin, titanium dioxide, FD&C Yellow #6, FD&C Red #3, FD&C Red #40, shellac and black iron oxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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