VIIBRYD™ (vilazodone hydrochloride) Tablets

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VIIBRYD™ safely and effectively. See full prescribing information for VIIBRYD.

VIIBRYD (vilazodone HCl) Tablets for oral administration
Initial U.S. Approval: 2011

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

See full prescribing information for complete boxed warning.
Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders (5.1).
VIIBRYD is not approved for use in pediatric patients (8.4).

INDICATIONS AND USAGE

VIIBRYD is indicated for the treatment of major depressive disorder (MDD). The efficacy of VIIBRYD was established in two 8-week, placebo-controlled trials in adult patients with MDD (1, 14).

DOSAGE AND ADMINISTRATION

- The recommended dose for VIIBRYD is 40 mg once daily (2).
- VIIBRYD should be titrated to the 40 mg dose, starting with an initial dose of 10 mg once daily for 7 days, followed by 20 mg once daily for an additional 7 days, and then increased to 40 mg once daily (2).
- VIIBRYD should be taken with food. Administration without food can result in inadequate drug concentrations and may diminish effectiveness (2, 12.3).
- When discontinuing treatment, reduce the dose gradually (2.4).

DOSAGE FORMS AND STRENGTHS

VIIBRYD is available as 10 mg, 20 mg and 40 mg tablets (3).

CONTRAINDICATIONS

- **Monoamine Oxidase Inhibitors**: Do not use VIIBRYD concomitantly with an MAOI or within 14 days of stopping or starting an MAOI (4.1).

WARNINGS AND PRECAUTIONS

Clinical Worsening/Suicide Risk: Monitor patients for clinical worsening and suicidal thinking or behavior (5.1).
Serotonin Syndrome or Neuroleptic Malignant (NMS)-like Syndrome: Can occur with treatment. Discontinue and initiate supportive treatment (5.2).
Seizures: Can occur with treatment. Use with caution in patients with a seizure disorder (5.3).
Abnormal Bleeding: Treatment can increase the risk of bleeding. Use with caution in association with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation (5.4).
Activation of Mania/Hypomania: Can occur with treatment. Screen patients for bipolar disorder (5.5).
Discontinuation of Treatment with VIIBRYD: A gradual reduction in dose is recommended rather than an abrupt cessation (5.6).
Hyponatremia: Can occur in association with the syndrome of inappropriate antidiuretic hormone secretion (SIADH) (5.7).

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥ 5% and at least twice the rate of placebo) are: diarrhea, nausea, vomiting, and insomnia (6).
To report SUSPECTED ADVERSE REACTIONS, contact Trovis Pharmaceuticals at 1-877-878-7200 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

MAOIs: Do not use VIIBRYD concomitantly with an MAOI or within 14 days of stopping or starting an MAOI (4.1, 7.1).
CYP3A4 inhibitors: The VIIBRYD dose should be reduced to 20 mg when co-administered with CYP3A4 strong inhibitors (7.3).
CYP3A4 inducers: Concomitant use of VIIBRYD with inducers of CYP3A4 can result in inadequate drug concentrations and may diminish effectiveness. The effect of CYP3A4 inducers on systemic exposure of vilazodone has not been evaluated (7.3).

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no controlled human data regarding VIIBRYD use during pregnancy. Use only if the potential benefits outweigh the potential risks (2.3, 8.1).
Nursing Mothers: There are no human data regarding VIIBRYD concentrations in breast milk. Women should breast feed only if the potential benefits outweigh the potential risks (8.3, 2.3).
Pediatric Use: The safety and efficacy of VIIBRYD in pediatric patients have not been studied (8.4).
Geriatric Use: No dose adjustment is recommended on the basis of age (8.5).
Hepatic Impairment: No dose adjustment is recommended in patients with mild or moderate hepatic impairment. VIIBRYD has not been studied in patients with severe hepatic impairment (8.6).
Renal Impairment: No dose adjustment is recommended in patients with mild, moderate, or severe renal impairment. (8.7).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: January 2010

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FULL PRESCRIBING INFORMATION

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of VIIBRYD or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. VIIBRYD is not approved for use in pediatric patients [*see Warnings and Precautions (5.1), Use in Specific Populations (8.4), and Patient Counseling Information (17.1)*]

1 INDICATIONS AND USAGE

VIIBRYD is indicated for the treatment of major depressive disorder (MDD). The efficacy of VIIBRYD was established in two 8-week, randomized, double-blind, placebo-controlled trials in adult patients with a diagnosis of MDD *[see Clinical Studies (14)].*

Major depressive disorder consists of one or more major depressive episodes. A major depressive episode (DSM-IV-TR) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least 5 of the following 9 symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, or a suicide attempt or suicidal ideation.

2 DOSAGE AND ADMINISTRATION

2.1 Initial Treatment of Major Depressive Disorder

The recommended dose for VIIBRYD is 40 mg once daily. VIIBRYD should be titrated, starting with an initial dose of 10 mg once daily for 7 days, followed by 20 mg once daily for an additional 7 days, and then an increase to 40 mg once daily. VIIBRYD should be taken with food. VIIBRYD blood concentrations (AUC) in the fasted state can be decreased by approximately 50% compared to the fed state, and may result in diminished effectiveness in some patients *[see Pharmacokinetics (12.3)]*.

2.2 Maintenance/Continuation/Extended Treatment

The efficacy of VIIBRYD has not been systematically studied beyond 8 weeks. It is generally agreed that acute episodes of major depressive disorder require several months or longer of sustained pharmacologic therapy. Patients should be reassessed periodically to determine the need for maintenance treatment and the appropriate dose for treatment.

2.3 Dosing in Special Populations

Pregnant Women: Neonates exposed to serotonergic antidepressants late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. When treating pregnant women with VIIBRYD, consider whether the potential benefits outweigh the potential risks of treatment *[see Pregnancy (8.1)]*.

Nursing Mothers: There are no clinical data regarding the effect of VIIBRYD on lactation and nursing *[see Nursing Mothers (8.3)]*. Breastfeeding in women treated with VIIBRYD should be considered only if the potential benefit outweighs the potential risk.

Pediatric Patients: The safety and efficacy of VIIBRYD have not been studied in pediatric patients *[see Pediatric Use (8.4)]*.

Geriatric Patients: No dose adjustment is recommended on the basis of age *[see Geriatric Use (8.5)]*.

Hepatic Impairment: No dose adjustment is recommended in patients with mild or moderate hepatic impairment. VIIBRYD has not been studied in severe hepatic impairment *[see Hepatic Impairment (8.6)]*.

Renal Impairment: No dose adjustment is recommended in patients with mild, moderate, or severe renal impairment. *[see Renal Impairment (8.7)]*.

Gender: No dose adjustment is recommended on the basis of gender *[see Gender Effect (8.8)]*.

2.4 Discontinuing Treatment

Discontinuation symptoms have been reported with discontinuation of serotonergic drugs such as VIIBRYD. Gradual dose reduction is recommended, instead of abrupt discontinuation, whenever possible. Monitor patients for these symptoms when discontinuing VIIBRYD. If intolerable symptoms occur following a dose decrease or upon discontinuation of treatment, consider resuming the previously prescribed dose and decreasing the dose at a more gradual rate *[see Warnings and Precautions (5.6)]*.

2.5 Monoamine Oxidase Inhibitors (MAOI)

At least 14 days must elapse between discontinuation of an MAOI and initiation of therapy with VIIBRYD. In addition, at least 14 days must be allowed after stopping VIIBRYD before starting an MAOI *[see Contraindications (4.1)]*.

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3 DOSAGE FORMS AND STRENGTHS

VIIBRYD Tablets are available as 10 mg, 20 mg and 40 mg immediate-release, film-coated tablets.

- 10 mg pink, oval tablet, debossed with 10 on one side
- 20 mg orange, oval tablet, debossed with 20 on one side
- 40 mg blue, oval tablet, debossed with 40 on one side

4 CONTRAINDICATIONS

4.1 Monoamine Oxidase Inhibitors

VIIBRYD must not be used concomitantly in patients taking MAOIs or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. These interactions have been associated with symptoms that include tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness, hyperthermia with features resembling neuroleptic malignant syndrome, seizures, rigidity, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. Allow at least 14 days after stopping VIIBRYD before starting an MAOI *[see Drug Interactions (7.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Clinical Worsening and Suicide Risk

Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled studies of antidepressant drugs (selective serotonin reuptake inhibitors [SSRIs] and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with MDD and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.

The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 295 short-term studies (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs. placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1.

Table 1

Age Range	**Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated**
	Increases Compared to Placebo
<18	14 additional cases
18-24	5 additional cases
	Decreases Compared to Placebo
25-64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms [*see Warnings and Precautions (5.6) and Dosage and Administration (2.4)*].

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as

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the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for VIIBRYD should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose *[see also Patient Counseling Information (17.1)]*.

Screening patients for bipolar disorder
A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled studies) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that VIIBRYD is not approved for use in treating bipolar depression.

5.2 Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions
The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions has been reported with antidepressants alone, but particularly with concomitant use of serotonergic drugs (including triptans) with drugs that impair metabolism of serotonin (including MAOIs), or with antipsychotics or other dopamine antagonists. Symptoms of serotonin syndrome were noted in 0.1% of patients treated with VIIBRYD. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Serotonin syndrome, in its most severe form can resemble NMS, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms.

The concomitant use of VIIBRYD with MAOIs intended to treat depression is contraindicated. *[see Contraindications (4.1)]*.

If concomitant treatment of VIIBRYD with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases *[see Drug Interactions (7.1)]*.

The concomitant use of VIIBRYD with serotonin precursors (such as tryptophan) is not recommended *[see Drug Interactions (7.1)]*.

Treatment with VIIBRYD and any concomitant serotonergic (SSRI, serotonin–norepinephrine reuptake inhibitor [SNRI], triptan, buspirone, tramadol, etc.) or antidopaminergic drugs, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.

5.3 Seizures
VIIBRYD has not been systematically evaluated in patients with a seizure disorder. Patients with a history of seizures were excluded from clinical studies. Like other antidepressants, VIIBRYD should be prescribed with caution in patients with a seizure disorder.

5.4 Abnormal Bleeding
The use of drugs that interfere with serotonin reuptake inhibition, including VIIBRYD, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDS), warfarin, and other anticoagulants may add to this risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to SSRIs have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages.

Patients should be cautioned about the risk of bleeding associated with the concomitant use of VIIBRYD and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding.

5.5 Activation of Mania/Hypomania
Symptoms of mania/hypomania were reported in 0.1% of patients treated with VIIBRYD in clinical studies. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other antidepressants. As with all antidepressants, use VIIBRYD cautiously in patients with a history or family history of bipolar disorder, mania, or hypomania.

5.6 Discontinuation of Treatment with VIIBRYD
There have been reports of adverse events occurring upon discontinuation of serotonergic antidepressants, particularly when discontinuation is abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesia, such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms.

Monitor patients for these symptoms when discontinuing VIIBRYD. Reduce the dose gradually whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, consider resuming the previously prescribed dose. Subsequently, the dose may be decreased, but at a more gradual rate *[see Dosage and Administration, (2.4)]*.

5.7 Hyponatremia
Although no cases of hyponatremia resulting from VIIBRYD treatment were reported in the clinical studies, hyponatremia has occurred as a result of treatment with SSRIs and SNRIs. In many cases, hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Cases with serum sodium lower than110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs. Also, patients taking diuretics or who are otherwise volume depleted can be at greater risk. Discontinuation of VIIBRYD in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which can lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience
The most commonly observed adverse reactions in VIIBRYD-treated MDD patients in placebo-controlled studies (incidence ≥ 5% and at least twice the rate of placebo) were: diarrhea, nausea, vomiting, and insomnia.

Patient Exposure

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