

HIGHLIGHTS OF PRESCRIBING INFORMATION

The following information is provided to assist you in making the most informed decision on the use of OLANZAPINE ORALLY DISINTEGRATING TABLETS safely and effectively. See full prescribing information for OLANZAPINE ORALLY DISINTEGRATING TABLETS.

OLANZAPINE ORALLY DISINTEGRATING tablets, for oral use
Initial U.S. Approval: 1996

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

See full prescribing information for complete boxed warning.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Olanzapine orally disintegrating tablets are not approved for use in elderly patients with dementia-related psychosis (5.1, 5.4, 17.2).
- When using olanzapine and fluoxetine in combination, also refer to the Boxed Warning section of the package insert for Symbyax.

INDICATIONS AND USAGE

Olanzapine is an atypical antipsychotic indicated:

- As oral formulation for the:
 - Treatment of schizophrenia. (1.1)
 - Adults: Efficacy was established in three clinical trials in patients with schizophrenia. Two 6-week trials and one maintenance trial. (14.1)
 - Adolescents (ages 13 to 17): Efficacy was established in one 6-week trial in patients with schizophrenia (14.1). The increased potential (in adolescents compared with adults) for weight gain and dyslipidemia may lead clinicians to consider prescribing other drugs first in adolescents. (1.1)
 - Acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder. (1.2)
 - Adults: Efficacy was established in three clinical trials in patients with manic or mixed episodes of bipolar I disorder: two 3- to 4-week trials and one maintenance trial. (14.2)
 - Adolescents (ages 13 to 17): Efficacy has been reported in patients with manic or mixed episodes associated with bipolar I disorder (14.2). The increased potential (in adolescents compared with adults) for weight gain and dyslipidemia may lead clinicians to consider prescribing other drugs first in adolescents. (1.2)
 - Medication therapy for pediatric bipolar I disorder with schizophrenia or bipolar I disorder should be undertaken only after a thorough diagnostic evaluation and with careful consideration of the potential risks. (1.3)
 - Adjunct to valproate or lithium in the treatment of manic or mixed episodes associated with bipolar disorder. (1.2)
 - Efficacy was established in two 6-week clinical trials in adults (14.2). Maintenance efficacy has not been systematically evaluated.
- As Olanzapine and Fluoxetine in Combination for the:
- Treatment of depressive episodes associated with bipolar I disorder. (1.5)
 - Efficacy was established with Symbyax (olanzapine and fluoxetine in combination); refer to the product label for Symbyax.
 - Treatment of treatment resistant depression. (1.6)
 - Efficacy was established with Symbyax (olanzapine and fluoxetine in combination) in adults; refer to the product label for Symbyax.

DOSAGE AND ADMINISTRATION

Schizophrenia in adults (2.1)	Oral: Start at 5 to 10 mg once daily; Target: 10 mg/day with several days.
Schizophrenia in adolescents (2.1)	Oral: Start at 2.5 to 5 mg once daily; Target: 10 mg/day
Bipolar I Disorder (manic or mixed episodes) in adults (2.2)	Oral: Start at 10 or 15 mg once daily
Bipolar I Disorder (manic or mixed episodes) in adolescents (2.2)	Oral: Start at 2.5 to 5 mg once daily; Target: 10 mg/day
Bipolar I Disorder (manic or mixed episodes) with lithium or valproate in adults (2.2)	Oral: Start at 10 mg once daily
Depressive Episodes associated with Bipolar I Disorder in adults (2.5)	Oral in combination with fluoxetine: Start at 5 mg of oral olanzapine and 20 mg of fluoxetine once daily
Depressive Episodes associated with Bipolar I Disorder in children and adolescents (2.5)	Oral in combination with fluoxetine: Start at 2.5 mg of oral olanzapine and 20 mg of fluoxetine once daily
Treatment Resistant Depression in adults (2.6)	Oral in combination with fluoxetine: Start at 5 mg of oral olanzapine and 20 mg of fluoxetine once daily

Lower starting dose recommended in debilitated or pharmacodynamically sensitive patients or patients with predisposition to hypotensive reactions, or with potential for slowed metabolism. (2.1)

- Olanzapine may be given without regard to meals. (2.1)

Olanzapine and Fluoxetine in Combination:

- Dosage adjustments should be made with the individual components according to efficacy and tolerability. (2.5, 2.6)
- Olanzapine monotherapy is not indicated for the treatment of depressive episodes associated with bipolar I disorder or treatment resistant depression. (2.5, 2.6)
- Safety of coadministration of doses above 18 mg olanzapine with 75 mg fluoxetine has not been evaluated in adults. (2.5, 2.6)
- Safety of coadministration of doses above 12 mg olanzapine with 50 mg fluoxetine has not been evaluated in children and adolescents 10 to 17. (2.5)

DOSAGE FORMS AND STRENGTHS

- Orally Disintegrating Tablets (not scored): 5, 10, 15, 20 mg (3)

FULL PRESCRIBING INFORMATION: CONTENTS

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

1 INDICATIONS AND USAGE	1.1 Schizophrenia	1.2 Bipolar I Disorder (Manic or Mixed Episodes)	1.3 Special Considerations in Treating Pediatric Schizophrenia and Bipolar I Disorder	1.4 Olanzapine and Fluoxetine in Combination; Depressive Episodes Associated with Bipolar I Disorder	1.5 Olanzapine and Fluoxetine in Combination; Treatment Resistant Depression											
2 DOSAGE AND ADMINISTRATION	2.1 Schizophrenia	2.2 Bipolar I Disorder (Manic or Mixed Episodes)	2.3 Administration of Olanzapine Orally Disintegrating Tablets	2.5 Olanzapine and Fluoxetine in Combination; Depressive Episodes Associated with Bipolar I Disorder	2.6 Olanzapine and Fluoxetine in Combination; Treatment Resistant Depression											
3 DOSAGE FORMS AND STRENGTHS	3.1 Olanzapine	3.2 Olanzapine and Fluoxetine in Combination; Dosing in Special Populations														
4 CONTRAINDICATIONS																
5 WARNINGS AND PRECAUTIONS	5.1 Elderly Patients with Dementia-Related Psychosis	5.2 Suicide	5.3 Neuroleptic Malignant Syndrome (NMS)	5.4 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)	5.5 Metabolic Changes	5.6 Tardive Dyskinesia	5.7 Orthostatic Hypotension	5.8 Leukopenia, Neutropenia, and Agranulocytosis	5.9 Dysphagia	5.10 Seizures	5.11 Potential for Cognitive and Motor Impairment	5.12 Body Temperature Regulation	5.13 Use in Patients with Concomitant Illness	5.14 Hyperprolactinemia	5.15 Combination with Fluoxetine, Lithium, or Valproate	5.16 Laboratory Tests
6 ADVERSE REACTIONS	6.1 Clinical Trials Experience	6.2 Postmarketing Experience	6.3 Other Adverse Reactions	6.4 Postmarketing Experience												
7 DRUG INTERACTIONS	7.1 Potential for Other Drugs to Affect Olanzapine															

FULL PRESCRIBING INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of several placebo-controlled trials (median duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. In patients taking olanzapine, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the cause of death was varied, most of the deaths were attributed to pneumonia, sudden cardiac death, or infectious diseases (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality, but that the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristics of the patients is not clear. Olanzapine is not approved for use in elderly patients with dementia-related psychosis (see Warnings and Precautions (5.1, 5.4) and Patient Counseling Information (17.2)).

When using olanzapine and fluoxetine in combination, also refer to the Boxed Warning section of the package insert for Symbyax.

INDICATIONS AND USAGE

Olanzapine is indicated for the treatment of schizophrenia. Efficacy was established in three clinical trials in adult patients with schizophrenia: two 6-week trials and one maintenance trial. In adolescent patients with schizophrenia (ages 13 to 17), efficacy was established in one 6-week trial (see Clinical Studies (14.1)).

When deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and dyslipidemia. Clinicians should consider the potential long-term risks when treating adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents (see Warnings and Precautions (5.6)).

1.2 Bipolar I Disorder (Manic or Mixed Episodes)

Olanzapine is indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder. Efficacy was established in three clinical trials in adult patients with manic or mixed episodes of bipolar I disorder: two 3- to 4-week trials and one maintenance trial. In adolescent patients with manic or mixed episodes of bipolar I disorder (ages 13 to 17), efficacy was established in one 3-week trial (see Clinical Studies (14.2)).

When deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and dyslipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents (see Warnings and Precautions (5.6)).

1.3 Special Considerations in Treating Pediatric Schizophrenia and Bipolar I Disorder

Pediatric schizophrenia and bipolar I disorder are serious mental disorders; however, diagnosis can be challenging. For pediatric schizophrenia, symptom profiles are variable, and for bipolar I disorder, episodes are periodic or episodic. The diagnosis of schizophrenia or mixed episodes is not clear. It is recommended that medication therapy for pediatric schizophrenia and bipolar I disorder be initiated only after a thorough diagnostic evaluation and with careful consideration given to the risks associated with medication treatment. Medication treatment for both pediatric schizophrenia and bipolar I disorder should be part of a total treatment program that includes psychological, educational and social interventions.

CONTRAINDICATIONS

- None with olanzapine monotherapy.
- When using olanzapine and fluoxetine in combination, also refer to the Contraindications section of the package insert for Symbyax® (4).

When using olanzapine in combination with lithium or valproate, refer to the Contraindications section of the package inserts for those products.

WARNINGS AND PRECAUTIONS

- Elderly Patients with Dementia-Related Psychosis:** Increased risk of death and increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack). (5.1)
- Suicide:** The possibility of a suicide attempt is inherent in schizophrenia and in bipolar I disorder, and close supervision of high-risk patients should accompany drug therapy; when using in combination with fluoxetine, also refer to the Boxed Warning and Warnings and Precautions sections of the package insert for Symbyax. (5.2)
- Neuroleptic Malignant Syndrome:** Manage with immediate discontinuation and close monitoring. (5.3)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** Discontinue if DRESS is suspected. (5.4)
- Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. (5.5)
- Hyperglycemia and Diabetes Mellitus:** In some cases extreme and associated with ketoacidosis or hyperosmolar coma. (5.5)
- Diabetes:** Patients taking olanzapine. Patients taking olanzapine should be monitored for symptoms of hyperglycemia and undergo fasting blood glucose testing at the beginning of, and periodically during, treatment. (5.5)
- Dyslipidemia:** Undesirable alterations in lipids have been observed. Appropriate clinical monitoring is recommended, including fasting lipid testing at the beginning of, and periodically during, treatment. (5.5)

- Weight Gain:** Potential consequences of weight gain should be considered. Patients should receive counseling about weight gain. (5.5)
- Tardive Dyskinesia:** Discontinue if clinically appropriate. (5.6)
- Orthostatic Hypotension:** Orthostatic hypotension associated with dizziness, tachycardia, bradycardia, and, in some patients, syncope, may occur especially during initial dose titration. Use caution in patients with cardiovascular disease, cerebrovascular disease, and those conditions that could affect hemodynamic responses. (5.7)
- Leukopenia, Neutropenia, and Agranulocytosis:** Has been reported with antipsychotics, including olanzapine. Patients with a history of a clinically significant low white blood cell count (WBC) or drug-induced neutropenia should be monitored. Olanzapine and fluoxetine in combination are not approved for use in elderly patients with dementia-related psychosis. (5.8)
- Seizures:** Use cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold. (5.9)
- Potential for Cognitive and Motor Impairment:** Has potential to impair judgment, thinking, and motor skills. Use caution when operating machinery. (5.12)
- Hyperprolactinemia:** May elevate prolactin levels. (5.13)
- Use in Combination with Lithium or Valproate:** Also refer to the package inserts for Symbyax, lithium, or valproate. (5.16)
- Laboratory Tests:** Monitor fasting blood glucose and lipid profiles at the beginning of, and periodically during, treatment. (5.17)

ADVERSE REACTIONS

Most common adverse reactions (≥5% and at least twice that for placebo) associated with:
Oral Olanzapine Monotherapy:
• Schizophrenia (Adults) – postural hypotension, constipation, weight gain, dizziness, personality disorder, akathisia (6.1)

• Schizophrenia (Adolescents) – sedation, weight increased, headache, increased appetite, dizziness, abnormal vision, fatigue, dry mouth (6.3)

- Manic or Mixed Episodes, Bipolar I Disorder (Adults) – asthenia, dry mouth, constipation, increased appetite, somnolence, bzipiness, tremor (6.1)
- Manic or Mixed Episodes, Bipolar I Disorder (Adolescents) – sedation, weight increased, increased appetite, headache, fatigue, dizziness, dry mouth, abdominal pain, pain in extremity (6.3)

Combination of Olanzapine and Lithium or Valproate:
• Manic or Mixed Episodes, Bipolar I Disorder (Adults) – dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia (6.1)

Olanzapine and Fluoxetine in Combination: Also refer to the Adverse Reactions section of the package insert for Symbyax.
Treatment Resistant Depression: Also refer to the Adverse Reactions section of the package insert for Symbyax.
Depressive Episodes Associated with Bipolar I Disorder: Also refer to the Adverse Reactions section of the package insert for Symbyax.

DRUG INTERACTIONS

- Diazepam:** May potentiate orthostatic hypotension. (7.1, 7.2)
- Alcohol:** May potentiate orthostatic hypotension. (7.1)
- Carbamazepine:** Increased clearance of olanzapine. (7.1)
- Anticholinergics:** May increase olanzapine levels. (7.1)
- Olanzapine and Fluoxetine in Combination:** Also refer to the Drug Interactions section of the package insert for Symbyax. (7.1)
- CNS-acting Drugs:** Caution should be used when taken in combination with other centrally acting drugs and alcohol. (7.1)
- Antihypertensive Agents:** Enhanced antihypertensive effect. (7.2)
- Levodopa and Dopamine Agonists:** May antagonize levodopa/dopamine agonists. (7.2)
- Other CNS-acting Drugs:** Caution should be used when taken in combination with other CNS-acting drugs and alcohol. (7.1)

USE IN SPECIFIC POPULATIONS

• **Pregnancy:** Olanzapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1)

• **Nursing Mothers:** Breast-feeding is not recommended. (8.3)

• **Children:** Safety and effectiveness of olanzapine in children <13 years of age have not been established. Safety and effectiveness of olanzapine and fluoxetine in combination in children <10 years of age have not been established. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and the FDA-approved Medication Guide. Revised: 09/2018

POTENTIAL FOR OLANZAPINE TO AFFECT OTHER DRUGS

- 7.2.1 Potential for Olanzapine to Affect Other Drugs**
- 7.2.2 Potential for Olanzapine to Affect Other Drugs**
- 8.1 Pregnancy**
- 8.2 Labor and Delivery**
- 8.3 Nursing Mothers**
- 8.4 Pediatric Use**
- 8.5 Geriatric Use**

DRUG ABUSE AND DEPENDENCE

Olanzapine is not a controlled substance.

OVERDOSAGE

- 10.1 Human Experience
- 10.2 Management of Overdose

CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics

NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 13.2 Animal Toxicology and/or Pharmacology

HOW SUPPLIED/STORAGE AND HANDLING

- 16.1 Storage and Handling
- 16.2 Storage and Handling

PATIENT COUNSELING INFORMATION

- 17.1 Information on Medication Guide
- 17.2 Elderly Patients with Dementia-Related Psychosis: Increased Mortality and Cerebrovascular Adverse Events (CVAE), Including Stroke
- 17.3 Neuroleptic Malignant Syndrome (NMS)
- 17.4 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- 17.5 Metabolic Changes
- 17.6 Storage and Handling
- 17.7 Weight Gain
- 17.8 Potential for Cognitive and Motor Impairment
- 17.9 Potential for Cognitive and Motor Impairment
- 17.10 Body Temperature Regulation
- 17.11 Concomitant Medication
- 17.12 Phenylethanolamines
- 17.13 Hyperprolactinemia
- 17.14 Use in Specific Populations
- 17.15 Need for Comprehensive Treatment Program in Pediatric Patients

*Sections or subsections omitted from the full prescribing information are not listed.

Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine and fluoxetine in combination is indicated for the treatment of depressive episodes associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine monotherapy is not indicated for the treatment of depressive episodes associated with bipolar I disorder.

Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine monotherapy is not indicated for the treatment of treatment resistant depression.

DOSAGE AND ADMINISTRATION

1.1 Schizophrenia

Dose Selection: – Oral olanzapine should be administered on a once-a-day schedule without regard to meals, generally beginning with 5 to 10 mg daily, with a target dose of 10 mg daily with several days. Further dosage adjustments, if indicated, should generally occur at intervals of not less than 1 week, since steady state for olanzapine would not be achieved for approximately 1 week in the typical patient. When dosage adjustments are necessary, dose increments/decrements of 2.5 or 5 mg are recommended.

Efficacy in schizophrenia was demonstrated in a dose range of 10 to 15 mg daily in clinical trials. However, doses above 10 mg/day were not demonstrated to be more efficacious than the 10 mg/day dose. An increase to a dose greater than the target dose of 10 mg/day (i.e., a dose of 15 mg/day or greater) is recommended only after clinical assessment. Olanzapine is not indicated for use in doses above 10 mg/day.

Dosing in Special Populations: – The recommended starting dose is 5 mg in patients who are debilitated, who have a predisposition to hypotensive reactions, or who are elderly (aged 65 years or older). (2.1)

1.2 Bipolar I Disorder (Manic or Mixed Episodes)

Dose Selection: – Oral olanzapine should be administered on a once-a-day schedule without regard to meals, with a recommended starting dose of 5 mg or 10 mg once daily. (2.2)

1.3 Special Considerations in Treating Pediatric Schizophrenia and Bipolar I Disorder

Maintenance Treatment: – The effectiveness of oral olanzapine, 10 mg/day to 20 mg/day, in maintaining treatment response in pediatric schizophrenia was demonstrated in a placebo-controlled trial in patients with schizophrenia. (14.1)

1.4 Olanzapine and Fluoxetine in Combination: Also refer to the Adverse Reactions section of the package insert for Symbyax.

1.5 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Dose Selection for Monotherapy: – Oral olanzapine should be administered on a once-a-day schedule without regard to meals, generally beginning with 5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.5)

beginning with 10 to 15 mg. Dosage adjustments, if indicated, should generally occur at intervals of not less than 24 hours, reflecting the procedures in the placebo-controlled trials. When dosage adjustments are necessary, dose increments/decrements of 5 mg QD are recommended.

Shown in 4 weeks) antmanic efficacy was demonstrated in a dose range of 5 mg to 20 mg/day in clinical trials. The safety of doses above 20 mg/day has not been evaluated in clinical trials (see Clinical Studies (14.2)).

Maintenance Monotherapy: – The benefit of maintaining bipolar I patients on monotherapy with oral olanzapine at a dose of 5 to 20 mg/day after achieving a responder status for an average duration of 2 weeks was demonstrated in a placebo-controlled trial (see Clinical Studies (14.2)). The physician who elects to use olanzapine for extended periods should periodically reevaluate the long-term usefulness of the drug for individual patients. When dosage adjustments are necessary, dose increments/decrements of 2.5 or 5 mg are recommended.

Dose Selection for Adjunctive Treatment: – When administered as adjunctive treatment to lithium or valproate, oral olanzapine dosing should generally begin with 10 mg once-a-day without regard to meals.

Antimanic efficacy was demonstrated in a dose range of 5 mg to 20 mg/day in clinical trials (see Clinical Studies (14.2)). The safety of doses above 20 mg/day has not been evaluated in clinical trials.

ADOLESCENTS

Dose Selection: – Oral olanzapine should be administered on a once-a-day schedule without regard to meals with a recommended starting dose of 5 mg or 10 mg once daily. (2.2)

Maintenance Treatment: – The efficacy of olanzapine for the maintenance treatment of bipolar I disorder in the adolescent population has not been systematically evaluated; however, maintenance efficacy can be extrapolated from adult data along with comparisons of pharmacokinetic parameters in adult and adolescent patients. Thus, it is generally recommended that responding patients be continued beyond the acute response, but at the lowest dose needed to maintain remission. Patients should be periodically reassessed to determine the need for continued treatment.

2.3 Administration of Olanzapine Orally Disintegrating Tablets

Olanzapine orally disintegrating tablets should be administered orally, immediately upon opening the blister, using dry hands, remove tablet and place entire olanzapine orally disintegrating tablet in the mouth. Tablet disintegration occurs rapidly in saliva so it can be easily swallowed with or without liquid.

2.4 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

When using olanzapine and fluoxetine in combination, also refer to the Clinical Studies section of the package insert for Symbyax.

ADULTS

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.5)

2.5 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.6 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.7 Olanzapine and Fluoxetine in Combination: Dosing in Special Populations

The starting dose of oral olanzapine 2.5 to 5 mg with fluoxetine 20 mg should be used for patients with a predisposition to hypotensive patients (e.g., elderly, debilitated, or who have cardiovascular disease), or who are elderly (aged 65 years or older). (2.5)

2.8 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.9 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.10 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.11 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.12 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.13 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.14 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.15 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.16 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.17 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.18 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.19 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.20 Olanzapine and Fluoxetine in Combination: Treatment Resistant Depression

Olanzapine and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder) associated with bipolar I disorder, based on clinical studies. When using olanzapine and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

2.21 Olanzapine and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Olanzapine should be administered in combination with fluoxetine once daily in the evening, without regard to meals, generally beginning with 2.5 mg of oral olanzapine and 20 mg of fluoxetine. Dosage adjustments, if indicated, can be made according to efficacy and tolerability. (2.6)

