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Patient Resource Guide

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2012

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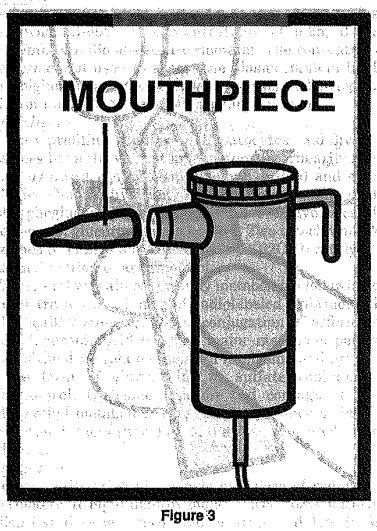

Figure 3

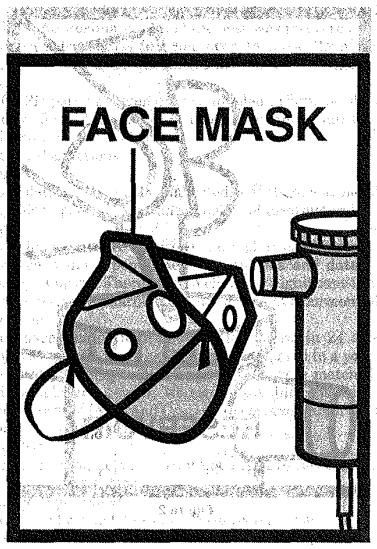

Figure 4

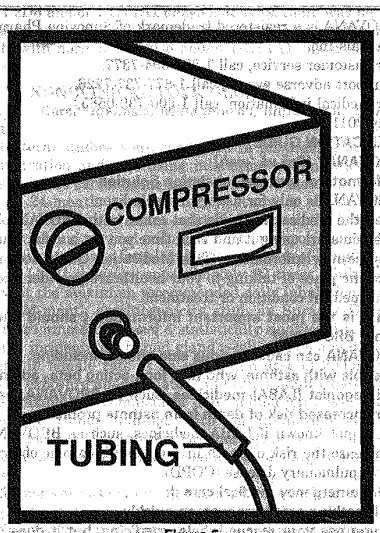

Figure 5

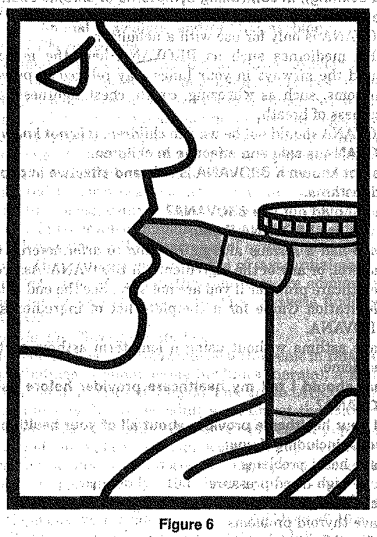
Figure 6

- If your COPD symptoms worsen over time do not increase your dose of BROVANA, instead call your healthcare provider.
- Increased blood pressure
- Fast or irregular heartbeat
- **serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems.** Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.

Common side effects of BROVANA include:

- **chest or back pain**
- **diarrhea**
- **sinus congestion**
- **headache**
- **tremor**
- **nervousness**
- **leg cramps**
- **high blood potassium**
- **shortness of breath**
- **rash**
- **fever**
- **increased white blood cells**
- **vomiting**
- **tiredness**
- **leg swelling**
- **chest congestion or bronchitis**

Tell your healthcare provider if you get any side effect that bothers you or that does not go away.

These are not all the side effects with BROVANA. Ask your healthcare provider or pharmacist for more information. 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 BROVANA?

- Store BROVANA in a refrigerator between 36° to 46°F (2° to 8°C) in the protective foil pouch. Protect from light and excessive heat. **Do not open a sealed pouch until you are ready to use a dose of BROVANA. After opening the pouch, unused ready-to-use vials should be returned to, and stored in, the pouch. An opened ready-to-use vial should be used right away.** BROVANA may be used directly from the refrigerator.
- BROVANA may also be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 6 weeks (42 days). If stored at room temperature, discard BROVANA if it is not used after 6 weeks or if past the expiration date, whichever is sooner. Space is provided on the packaging to record room temperature storage times.
- Do not use BROVANA after the expiration date provided on the foil pouch and ready-to-use vial.
- BROVANA should be colorless. Discard BROVANA if it is not colorless.
- **Keep BROVANA and all medicines out of the reach of children.**

General Information about BROVANA

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

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

- For customer service, call 1-888-394-7377.
- To report side effects, call 1-877-737-7226.
- For medical information, call 1-800-739-0565.

Instructions for Using BROVANA (arformoterol tartrate) Inhalation Solution

BROVANA is used only in a standard jet nebulizer machine connected to an air compressor. Make sure you know how to use your nebulizer machine before you use it to breathe-in BROVANA or other medicines.

Do not mix BROVANA with other medicines in your nebulizer machine.

BROVANA comes sealed in a foil pouch. Do not open a sealed pouch until you are ready to use a dose of BROVANA. After opening the pouch, unused ready-to-use vials should be returned to, and stored in, the pouch. An opened ready-to-use vial should be used right away.

1. Open the foil pouch by tearing on the rough edge along the seam of the pouch. Remove a ready-to-use vial of BROVANA.
2. Carefully twist open the top of the ready-to-use vial and use it right away (**Figure 1**).

[See figure 1 at top of previous page]

3. Squeeze all of the medicine from the ready-to-use vial into the nebulizer medicine cup (reservoir) (**Figure 2**).

[See figure 2 at top of previous page]

4. Connect the nebulizer reservoir to the mouthpiece (**Figure 3**) or face mask (**Figure 4**).

[See figure 3 at top of first column]
[See figure 4 at top of first column]

5. Connect the nebulizer to the compressor (**Figure 5**).

[See figure 5 at top of second column]

6. Sit in a comfortable, upright position. Place the mouthpiece in your mouth (**Figure 6**) (or put on the face mask) and turn on the compressor.

[See figure 6 at top of second column]

7. Breathe as calmly, deeply, and evenly as possible until no more mist is formed in the nebulizer reservoir. It takes about 5 to 10 minutes for each treatment.
8. Clean the nebulizer (see manufacturer's instructions).

Rx Only

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

SUNOVION

Manufactured for:
Sunovion Pharmaceuticals Inc.
Marlborough, MA 01752 USA

BROVANA is a registered trademark of Sunovion Pharmaceuticals Inc.

July 2011

Shown in Product Identification Guide, page 317

LATUDA ℞

(lurasidone HCl)
tablets for oral administration

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

LATUDA (LURASIDONE HCl) tablets for oral administration,

Initial U.S. Approval: 2010

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. LATUDA is not approved for the treatment of patients with dementia-related psychosis (*5.1*).

INDICATIONS AND USAGE

LATUDA is an atypical antipsychotic agent indicated for the treatment of patients with schizophrenia (*1*). Efficacy was established in four 6-week controlled studies of adult patients with schizophrenia (*14.1*).

DOSAGE AND ADMINISTRATION

The recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. The maximum recommended dose is 80 mg once daily. LATUDA should be taken with food (*2.2*).

DOSAGE FORMS AND STRENGTHS

Tablets: 40 mg and 80 mg (*3*)

CONTRAINDICATIONS

Any known hypersensitivity to LATUDA or any components in the formulation (*4*).

Coadministration with a strong CYP3A4 inhibitor (e.g., ketoconazole) and inducer (e.g., rifampin) (*4*).

WARNINGS AND PRECAUTIONS

- **Cerebrovascular Adverse Reactions:** An increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack) has been seen in elderly patients with dementia-related psychoses treated with atypical antipsychotic drugs. (*5.2*).
- **Neuroleptic Malignant Syndrome:** Manage with immediate discontinuation and close monitoring (*5.3*).
- **Tardive Dyskinesia:** Discontinue if clinically appropriate (*5.4*).
- **Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain (*5.5*).
- **Hyperglycemia and Diabetes Mellitus:** Monitor patients for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Monitor glucose regularly in patients with diabetes or at risk for diabetes.
- **Dyslipidemia:** Undesirable alterations have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Gain in body weight has been observed; clinical monitoring of weight is recommended.
- **Hyperprolactinemia:** Prolactin elevations may occur (*5.6*).
- **Leukopenia, Neutropenia, and Agranulocytosis** have been reported with antipsychotics. Patients with a pre-existing low white blood cell count (WBC) or a history of leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and LATUDA should be discontinued at the first sign of a decline in WBC in the absence of other causative factors (*5.7*).
- **Orthostatic Hypotension and Syncope:** Dizziness, tachycardia or bradycardia, and syncope may occur, especially early in treatment. Use with caution in patients with known cardiovascular or cerebrovascular disease, and in antipsychotic-naive patients (*5.8*).
- **Seizures:** Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold (*5.9*).
- **Potential for Cognitive and Motor Impairment:** Use caution when operating machinery (*5.10*).
- **Suicide:** The possibility of a suicide attempt is inherent in schizophrenia. Closely supervise high-risk patients (*5.12*).
- See Full Prescribing Information for additional **WARNINGS and PRECAUTIONS**.

ADVERSE REACTIONS

Commonly observed adverse reactions (incidence ≥ 5% and at least twice the rate for placebo) included somnolence, akathisia, nausea, parkinsonism and agitation (*6.2*).

To report SUSPECTED ADVERSE REACTIONS, contact Sunovion Pharmaceuticals Inc. at 877-737-7226 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- LATUDA is not recommended to be used in combination with strong CYP3A4 inhibitors, e.g., ketoconazole (*4* and *7.1*).
- Dose adjustment is recommended for moderate CYP3A4 inhibitors (e.g., diltiazem) (*7.1*).
- LATUDA is not recommended to be used in combination with strong CYP3A4 inducers, e.g., rifampin (*4* and *7.1*).

USE IN SPECIFIC POPULATIONS

- **Geriatric Use:** No dose adjustments required (*8.5*).
- **Pregnancy:** Use LATUDA during pregnancy only if the potential benefit justifies the potential risk (*8.1*).
- **Nursing Mothers:** Breast feeding is not recommended (*8.3*).
- **Pediatric Use:** Safety and effectiveness have not been established (*8.4*).
- **Renal Impairment:** Dose adjustment is recommended (*8.6*).
- **Hepatic Impairment:** Dose adjustment is recommended (*8.7*).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 05/2011

FULL PRESCRIBING INFORMATION: CONTENTS*

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

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 17 placebo-controlled trials (modal 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. Over the course of a typical 10-week controlled trial, 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 causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature.

Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear.

LATUDA is not approved for the treatment of patients with dementia-related psychosis. *[see Warnings and Precautions (5.1)]*.

1. INDICATIONS AND USAGE

LATUDA is indicated for the treatment of patients with schizophrenia.

The efficacy of LATUDA in schizophrenia was established in four 6-week controlled studies of adult patients with schizophrenia *[see Clinical Studies (14.1)]*.

The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient *[see Dosage and Administration (2)]*.

2. DOSAGE AND ADMINISTRATION

2.1. Schizophrenia

The recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg/day to 120 mg/day *[see Clinical Studies (14.1)]*. In the 6-week controlled trials, there was no suggestion of added benefit with the 120 mg/day dose, but there was a dose-related increase in certain adverse reactions. Therefore, the maximum recommended dose is 80 mg/day.

2.2. Administration Instructions

LATUDA should be taken with food (at least 350 calories) *[see Clinical Pharmacology (12)]*.

2.3. Dosage in Special Populations

Dosage adjustments are not recommended on the basis of age, gender, and race *[see Use in Specific Populations (8)]*.

Dose adjustment is recommended in moderate and severe renal impairment patients. The dose in these patients should not exceed 40 mg/day *[see Use in Specific Populations (8)]*.

Dose adjustment is recommended in moderate and severe hepatic impairment patients. The dose in these patients should not exceed 40 mg/day *[see Use in Specific Populations (8)]*.

Dosing recommendation for patients taking LATUDA concomitantly with potential CYP3A4 inhibitors: When coadministration of LATUDA with a moderate CYP3A4 inhibitor such as diltiazem is considered, the dose should not exceed 40 mg/day. LATUDA should not be used in combination with a strong CYP3A4 inhibitor (e.g., ketoconazole) *[see Contraindications (4); Drug Interactions (7.1)]*.

Dosing recommendation for patients taking LATUDA concomitantly with potential CYP3A4 inducers: LATUDA should not be used in combination with a strong CYP3A4 inducer (e.g., rifampin) *[see Contraindications (4); Drug Interactions (7.1)]*.

3. DOSAGE FORMS AND STRENGTHS

LATUDA tablets are available in the following shape and color (Table 1) with respective one-sided debossing: 40 mg (white to off-white, round, "L40"), or 80 mg (pale green, oval, "L80").

Table 1: LATUDA Tablet Presentations

Tablet Strength	Tablet Color/ Shape	Tablet Markings
40 mg	white to off-white round	L40
80 mg	pale green oval	L80

4. CONTRAINDICATIONS

LATUDA is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone *[see Adverse Reactions (6.6)]*.

LATUDA is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers (e.g., rifampin) *[see Drug Interactions (7.1)]*.

5. WARNINGS AND PRECAUTIONS

5.1. 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. LATUDA is not approved for the treatment of dementia-related psychosis *[see Boxed Warning]*.

Table 2: Change in Fasting Glucose

	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day
	Mean Change from Baseline (mg/dL)				
	n=438	n=71	n=352	n=270	n=283
Serum Glucose	-0.7	0.6	2.5	0.9	2.5
	Proportion of Patients with Shifts to ≥ 126 mg/dL				
Serum Glucose (≥ 126 mg/dL)	8.6% (34/397)	11.7% (7/60)	14.3% (47/328)	10.0% (24/241)	10.0% (26/260)

Table 3: Change in Fasting Lipids

	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day
	Mean Change from Baseline (mg/dL)				
	n=418	n=71	n=341	n=263	n=268
Total cholesterol	-8.5	-12.3	-9.4	-9.8	-3.8
Triglycerides	-15.7	-29.1	-6.2	-14.2	-3.1
	Proportion of Patients with Shifts				
Total cholesterol (≥ 240 mg/dL)	6.6% (23/350)	13.8% (8/58)	7.3% (21/287)	6.9% (15/216)	3.8% (9/238)
Triglycerides (≥ 200 mg/dL)	12.5% (39/312)	14.3% (7/49)	14.0% (37/264)	8.7% (17/196)	10.5% (22/209)

Table 4: Mean Change in Weight (kg) from Baseline

	Placebo (n=450)	LATUDA 20 mg/day (n=71)	LATUDA 40 mg/day (n=358)	LATUDA 80 mg/day (n=279)	LATUDA 120 mg/day (n=291)
All Patients	0.26	-0.15	0.67	1.14	0.68

5.2. Cerebrovascular Adverse Reactions, Including Stroke

In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly subjects with dementia, there was a higher incidence of cerebrovascular adverse reactions (cerebrovascular accidents and transient ischemic attacks), including fatalities, compared to placebo-treated subjects. LATUDA is not approved for the treatment of patients with dementia-related psychosis *[see also Boxed Warning and Warnings and Precautions (5.1)]*.

5.3. Neuroleptic Malignant Syndrome

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs, including LATUDA.

Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. It is important to exclude cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology.

The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. If reintroduced, the patient should be carefully monitored, since recurrences of NMS have been reported.

5.4. Tardive Dyskinesia

Tardive dyskinesia is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements that can develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, LATUDA should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on LATUDA, drug discontinuation should be considered. However, some patients may require treatment with LATUDA despite the presence of the syndrome.

5.5. Metabolic Changes

Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Because LATUDA was not marketed at the time these studies were performed, it is not known if LATUDA is associated with this increased risk.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the suspect drug.

Pooled data from short-term, placebo-controlled studies are presented in Table 2.

[See table 2 above]

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in glucose of +1.6 mg/dL at week 24 (n=186), +0.3 mg/dL at week 36 (n=236) and +1.2 mg/dL at week 52 (n=244).

Dyslipidemia

Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics. Pooled data from short-term, placebo-controlled studies are presented in Table 3.

[See table 3 above]

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in total cholesterol and triglycerides of -4.2 (n=186) and -13.6 (n=187) mg/dL at week 24, -1.9 (n=238) and -3.5 (n=238) mg/dL at week 36 and -3.6 (n=243) and -6.5 (n=243) mg/dL at week 52, respectively.

Weight Gain

Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Pooled data from short-term, placebo-controlled studies are presented in Table 4. The mean weight gain was 0.75 kg for LATUDA-treated patients compared to 0.26 kg for placebo-treated patients. In Study 3 *[see Clinical Studies (14.1)]* change in weight from baseline for olanzapine was 4.15 kg. The proportion of patients with a ≥ 7% increase in body weight (at Endpoint) was 5.6% for LATUDA-treated patients versus 4.0% for placebo-treated patients.

[See table 4 above]

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in weight of -0.38 kg at week 24 (n=531), -0.47 kg at week 36 (n=303) and -0.71 kg at week 52 (n=244).

5.6. Hyperprolactinemia

As with other drugs that antagonize dopamine D_2 receptors, LATUDA elevates prolactin levels.

Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotrophin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male patients *[see Adverse Reactions (6)]*.

In short-term, placebo-controlled studies, the median change from baseline to endpoint in prolactin levels for LATUDA-treated patients was 1.1 ng/mL and was -0.6 ng/mL in the placebo-treated patients. The increase in prolactin was greater in female patients; the median change from baseline to endpoint for females was 1.5 ng/mL and was 1.1 ng/mL in males. The increase in prolactin concentrations was dose-dependent (Table 5).

[See table 5 at top of next page]

The proportion of patients with prolactin elevations ≥ 6x ULN was 3.6% for LATUDA-treated patients versus 0.7%

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