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NEW ADULT INDICATION

The most common adverse events in pediatric trials included loss of appetite, insomnia, abdominal pain, and emotional lability. The most common adverse events in the adult trial included dry mouth, loss of appetite, insomnia, headache, and weight loss. The effectiveness of ADDERALL XR for long-term use has not been systematically evaluated in controlled trials. As with other psychostimulants indicated for ADHD, there is a potential for exacerbating motor and phonic tics and Tourette's syndrome. A side effect seen with the amphetamine class is psychosis. Caution also should be exercised in patients with a history of psychosis.

Abuse of amphetamines may lead to dependence. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events. ADDERALL XR generally should not be used in children or adults with structural cardiac abnormalities. ADDERALL XR is contraindicated in patients with symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism and glaucoma, known hypersensitivity to this class of compounds, agitated states, history of drug abuse, or current or recent use of MAO inhibitors. ADDERALL XR should be prescribed with close physician supervision.


www.ADDERALLXR.com
www.ADHDSupportCompany.com

Because he’s in AT HOME

Aim Higher With ADDERALL XR® —

Please see brief summary of prescribing information on adjacent page.
For Efficacy That Measures Up to Life's Demands

- Once-daily dosing provides all-day symptom control¹
- Mean ADHD-RS total scores for adults receiving ADDERALL XR decreased by 41%¹
- ADDERALL XR is the only stimulant medication approved to treat adults with ADHD¹
- Clinical data in adults demonstrate that ADDERALL XR is generally well tolerated¹
The premarketing development program for ADDERALL XR® included exposures in a total of 965 participants in clinical studies. ADDERALL XR® is recommended for use in children under 3 years of age.

**The Preclinical Pharmacology Studies**

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

- Carcinogenesis: Studies of amphetamine in rats and mice reveal the potential for amphetamine and its metabolites to induce tumors at certain sites. However, results of these studies should be interpreted with caution. The relationship of these findings to human risk is unknown.
- Mutagenesis: Studies in vitro and in vivo have been conducted to determine whether amphetamine is mutagenic or clastogenic. None of these studies has demonstrated any clastogenicity in the mouse bone marrow micronucleus test. In contrast, amphetamine was clastogenic in the mouse lymphoma tk assay, and was negative when tested in the £

- Impairment of Fertility: Prenatal or early postnatal exposure to amphetamine (d- or d,l-), at doses similar to those used clinically, can result in long-term neurochemical and behavioral alterations. Reported effects include impaired maternal behavior, alterations in brain dopamine receptor binding, and reduced body weight gain. Amphetamine administration during pregnancy in rodents and rabbits throughout the period of organogenesis at doses of up to 60 mg/kg/day (approximately 5 times the maximum recommended human dose of 30 mg/day [child] on a mg/m 1 body surface area basis)

**Pregnancy**

- Pregnancy Category C: Risk can be determined when chronic amphetamine use is considered. The potential for drug-induced fetal abnormalities has not been adequately studied in humans. However, in animals, amphetamine-induced maternal toxicity has been associated with decreased offspring size and increased resorptions. Administration of a cathartic and sedation. Experience with hemodialysis or peritoneal dialysis is inadequate to evaluate efficacy of dialysis in amphetamine intoxication.

**Postmarketing Experience**

- General: No deaths have been reported in patients taking ADDERALL XR®, especially patients with hypertension.
- Tachyphylaxis: Amphetamines have been reported to cause tachyphylaxis (tolerance) to their stimulant effects, including agitation, irritability, and insomnia. Tachyphylaxis can occur with both the immediate-release and extended-release forms of amphetamine.
- Abnormalities and Loss of Antibody Response: Amphetamines have been reported to cause alterations in antibody production, particularly in patients with autoimmune conditions. In some cases, this may lead to a decrease in the effectiveness of immunizations.
- Adverse Reactions: Adverse reactions to amphetamines can include a wide range of effects, from mild to severe. These may include:
  - CNS: Restlessness, irritability, agitation, hallucinations, tachycardia, tremors, seizures. Rarely, foci of nerve cell death in the brain have occurred.
  - Cardiovascular: Arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, dyspepsia, and diarrhea.
  - Psychiatric: Agitated states. Patients with a history of drug abuse. Opiate abusers have been reported to experience withdrawal symptoms on abrupt withdrawal of amphetamines. The withdrawal syndrome in opiate abusers is characterized by restlessness, insomnia, anxiety, irritability, and a lack of energy. In severe cases, delirium tremens can occur, characterized by delusions, hallucinations, and agitation.
  - Endocrine: Amenorrhea, hirsutism, and galactorrhea have been reported in women taking amphetamines.
  - Respiratory: Tachypnea, wheezing, and dyspnea have been reported in patients taking amphetamines.
  - Skin: Rash, pruritus, and urticaria can occur in patients taking amphetamines. In rare cases, Stevens-Johnson syndrome or toxic epidermal necrolysis (Lyell's syndrome) has been reported.
  - Renal: Acute renal failure has been reported in patients taking amphetamines. The risk of acute renal failure is increased in patients with dehydration or pre-existing renal impairment.

- Treatment of overdose: Treatment should be aimed at correcting any physiological abnormalities caused by amphetamine overdose. Supportive care, including monitoring of vital signs, should be provided. Gastrointestinal decontamination, including induced emesis and activated charcoal, may be beneficial in management of overdose. Hemodialysis may be considered in severe cases. Vomiting and diarrhea may aid in the removal of amphetamines from the body.

- Management of overdose: The management of amphetamine overdose should be tailored to the individual patient. Supportive care, including monitoring of vital signs, should be provided. Gastrointestinal decontamination, including induced emesis and activated charcoal, may be beneficial in management of overdose. Hemodialysis may be considered in severe cases. Vomiting and diarrhea may aid in the removal of amphetamines from the body.

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The Anxiety Disorders Association of America announces its 2005 Awards Program Call for Applications Available online at www.adaa.org

CAREER DEVELOPMENT TRAVEL AWARD - $3,500
Deadline: Tuesday, November 30, 2004

JUNIOR FACULTY RESEARCH GRANT - $30,000
Deadline: Tuesday, December 9, 2004

TRAINEE TRAVEL AWARD - $1,500
Deadline: Monday, December 20, 2004

Fifteen awardees are selected to attend the ADAA’s 25th Annual Conference, March 17-20, 2005, in Seattle, Washington. To date, the ADAA Awards Program has given more than 75 travel awards and 15 research grants, totaling nearly $700,000.

For award descriptions, eligibility requirements, award criteria, and applications, please visit the ADAA Web site at www.adaa.org. For more information, contact the ADAA Awards program manager, Jane Caroline Parham, at (P) 240-485-1016, (F) 240-485-1035, or email at jparham@adaa.org.

About the ADAA
The ADAA is the only national, nonprofit partnership of researchers, health care professionals, and individuals dedicated solely to the early diagnosis, prevention, and treatment of anxiety disorders. It is the Association’s goal to promote professional and public awareness and understanding of anxiety disorders. It also seeks to increase the availability of effective treatment, reduce the stigma surrounding anxiety disorders, and stimulate research.
The effectiveness of SEROQUEL in long-term use that is for more than 6 weeks has not been systematically studied. SEROQUEL for extended periods should periodically re-evaluate the long-term risks and benefits of the drug for each patient. Although it is not known whether antipsychotic drugs cross the placenta, newborns and infants of mothers taking antipsychotic drugs should be monitored for extrapyramidal and/or sedative effects. The syndrome of akathisia may be seen in the newborn of a mother treated with dopamine-blocking agents. The syndrome is characterized by extreme motor activity involving a combination of stereotypes, omission of purposeful movements, and overactivity without particular direction. The syndrome may be prevented by discontinuation of the drug. The syndrome may be prevented by discontinuation of the drug. The syndrome may be prevented by discontinuation of the drug.

Body Temperature Regulation: Although not reported with SEROQUEL, disruption of the body’s temperature regulation has been associated with antipsychotic drugs. Adverse reactions such as hyperpyrexia, hyperthermia, and “heat stroke” have been associated with antipsychotic drugs. These events may be more frequent with the use of antipsychotic drugs in patients with severe infections or with concurrent use of antipsychotic drugs and other drugs that impair cooling, such as anticholinergics, sedative-hypnotics, or sympathomimetics. When patients with these conditions receive antipsychotic drugs, routine monitoring of temperature is advised, especially when other drugs that impair cooling are used concomitantly. The use of antipsychotic drugs should be considered in these patients only if the benefits are considered to outweigh the risks.

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 creatine phosphokinase, rhabdomyolysis, and increased blood urea nitrogen. The syndrome is characterized by an elevation of body temperature, rigidity, mental status changes, and autonomic instability without evidence of infection. The medication must be withdrawn if the syndrome occurs. The clinical features of the syndrome are almost invariably present at the onset of the syndrome and may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and there-
SEROQUEL is indicated for the treatment of acute manic episodes associated with bipolar I disorder and the treatment of schizophrenia. Patients should be periodically reassessed to determine the need for continued treatment.

Prescribing should be consistent with the need to minimize the risk of tardive dyskinesia, seizures, and orthostatic hypotension. A rare condition referred to as neuroleptic malignant syndrome (NMS) has been reported with this class of medications, including SEROQUEL.

There have been reports of diabetes mellitus and hyperglycemia-related adverse events associated with the use of atypical antipsychotics, including SEROQUEL.

The most commonly observed adverse events associated with the use of SEROQUEL in clinical trials were somnolence, dry mouth, dizziness, constipation, asthenia, abdominal pain, postural hypotension, pharyngitis, SGPT increase, dyspepsia, and weight gain.
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EDITORIAL MISSION
CNS Spectrums' editorial mission is to address relevant neuropsychiatric topics, including the prevalence of comorbid diseases among patients, and original research and reports that emphasize the profound diagnostic and physiologic connections made within the neurologic and psychiatric fields. The journal's goal is to serve as a resource to psychiatrists and neurologists seeking to understand and treat disturbances of cognition, emotion, and behavior as a direct consequence of central nervous system disease, illness, or trauma.
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Unmasking Bipolar Disorder: Overcoming the Barriers to Treatment Success
By Roger S. McIntyre, MD, Jakub Z. Konarski, MSc, Prakash S. Masand, MD, Farhan S. Fazal, MBBS, Ashwin A. Patkar, MD, Michael W. Otto, PhD, and David J. Miklowitz, PhD

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Abilify. Now Indicated For Bipolar Mania.

Imagine where this could lead

Abilify is indicated for the treatment of schizophrenia and acute manic and mixed episodes associated with bipolar disorder.

IMPORTANT SAFETY INFORMATION

As with all antipsychotic medications, a rare condition referred to as neuroleptic malignant syndrome (NMS) has been reported. As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of tardive dyskinesia (TD).

Hyperglycemia, including some serious cases ranging from ketoacidosis to death, has been reported in patients treated with atypical antipsychotics. Abilify was not included in epidemiologic studies suggesting this risk; therefore the risk of hyperglycemia with Abilify is not known. However, there have been few reports of hyperglycemia in patients treated with Abilify. Patients should be appropriately tested before and monitored during treatment.

Abilify may be associated with orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

As with other antipsychotic drugs, Abilify should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold. Seizures occurred in 0.3% of bipolar patients treated with Abilify in placebo-controlled trials.

Patients should not drive or operate heavy machinery until they are certain Abilify does not affect them adversely.

Commonly observed adverse events reported with Abilify in 3-week bipolar mania trials at a >5% incidence for Abilify and at a rate at least twice the rate of placebo include, respectively, akathisia (15% vs 4%), constipation (13% vs 6%), and accidental injury (6% vs 3%).

Treatment-emergent adverse events reported with Abilify in short-term trials at an incidence ≥10% and greater than placebo, respectively, include headache (31% vs 26%), agitation (25% vs 24%), anxiety (20% vs 17%), insomnia (20% vs 15%), nausea (16% vs 12%), dyspepsia (15% vs 13%), somnolence (12% vs 8%), akathisia (12% vs 5%), lightheadedness (11% vs 8%), vomiting (11% vs 6%), and constipation (11% vs 7%).

The adverse events reported in a 26-week, double-blind schizophrenia trial comparing Abilify and placebo were generally consistent with those reported in the short-term, placebo-controlled schizophrenia trials, except for a higher incidence of tremor: 9% for Abilify vs 1% for placebo. In this study the majority of the cases of tremor were of mild intensity (9/13 mild and 4/13 moderate), occurred early in therapy (9/13 ≤49 days), and were of limited duration (9/13 ≤10 days). Tremor infrequently led to discontinuation (<1%) of Abilify. In addition, in a long-term (52-week), active-controlled study, the incidence of tremor for Abilify was 4%.

Please see Brief Summary of full Prescribing Information on following pages.

Visit www.abilify.com for more information.
Abrilimax®

(appriliprazole) Tablets

Brief Summary of Prescribing Information for complete prescribing information please consult official package circular.

INDICATIONS AND USAGE

Schizophrenia

Abrilimax® is indicated for the treatment of schizophrenia. The efficacy of Abrilimax® in the treatment of schizophrenia was established in short-term (4- and 6-week) controlled trials of schizophrenic inpatients (see CLINICAL PHARMACOLOGY: Clinical Studies in Full Prescribing Information). Abrilimax® was effective in the same patient population with aripiprazole in a single study in an outpatient setting (see CLINICAL PHARMACOLOGY: Clinical Studies in Outpatient Setting in Full Prescribing Information).

Abrilimax® was not studied in placebo-controlled studies in patients who were experiencing acute exacerbation of schizophrenia or patients with acute schizophrenia. Abrilimax® is indicated as an adjunct to a neuroleptic agent in treating patients with acute exacerbation of schizophrenia (see CLINICAL PHARMACOLOGY: Clinical Studies in Acute Schizophrenia in Full Prescribing Information). Abrilimax® is indicated as an adjunct to a neuroleptic agent in treating the acute exacerbation of schizophrenia in geriatric patients who are 65 years of age and older with a diagnosis of schizophrenia (see CLINICAL PHARMACOLOGY: Clinical Studies in Acute Schizophrenia in Geriatric Patients in Full Prescribing Information).

12% among placebo-treated patients and in bipolar mania: 3% among aripiprazole-treated patients and 2% among placebo-treated patients. 

Aripiprazole is not a substrate of CYP1A1, CYP3A, CYP2C8, CYP3A, CYP2C9, CYP2C19, or CYP2D6. 

The safety

PRECAUTIONS

General

Neuroleptic Malignant Syndrome (NMS)

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of a variety of antipsychotic drugs. The syndrome is characterized by the following clinical findings: increased body temperature (≥103°F orally), tachycardia, diaphoresis, and cardiac dysrhythmia. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated by the fact that the signs and symptoms of the NMS may overlap with the signs and symptoms of an acute episode of the patient's underlying illness. Therefore, patients with NMS should be carefully monitored. The potential need for drug discontinuation should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome.

Hyperphenylalaninemia

Aripiprazole has been shown to increase the plasma concentration of homovanillic acid, a metabolite of dopamine, thereby elevating the risk of inducing hyperphenylalaninemia in patients with phenylketonuria. When aripiprazole is used in these patients, appropriate treatment should be initiated to prevent the development of hyperphenylalaninemia. In patients with known hyperphenylalaninemia and abnormal tyrosine metabolism, the dose of aripiprazole should be reduced.

Use in Patients with Hyperprolactinemia

Aripiprazole has been shown to have a prolactin elevation effect in women and may cause an increase in prolactin levels in men. Therefore, appropriate use should be considered in patients with hyperprolactinemia or a history of prolactin elevations. Although the risk of prolactin elevations with aripiprazole is lower than with high-potency neuroleptics, the risk of hyperprolactinemia is still present.

Use in Patients with Renal Failure

Aripiprazole is metabolized primarily in the liver and excreted through the kidneys. In patients with renal impairment, the clearance of aripiprazole is reduced. Therefore, the dose of aripiprazole should be reduced in patients with moderate to severe renal impairment. The safety and efficacy of aripiprazole in patients with severe renal impairment (creatinine clearance <30 mL/min) have not been established. Use in these patients should be cautious.

Use in Patients with Hepatic Impairment

The metabolism of aripiprazole is primarily through the liver. However, aripiprazole is not a substrate of CYP3A4 and CYP2D6. Therefore, dose reductions are not necessary in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the dose of aripiprazole should be reduced.

Use in Patients with a History of Cardiovascular Disease

Aripiprazole should be used with caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease, or a family history of sudden death due to heart disease. The development of a potentially fatal symptom complex referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of a variety of antipsychotic drugs. The syndrome is characterized by the following clinical findings: increased body temperature (≥103°F orally), tachycardia, diaphoresis, and cardiac dysrhythmia. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated by the fact that the signs and symptoms of the NMS may overlap with the signs and symptoms of an acute episode of the patient's underlying illness. Therefore, patients with NMS should be carefully monitored. The potential need for drug discontinuation should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome.

Use in Patients with History of Gastrointestinal Disease

Aripiprazole is an antipsychotic drug and may cause gastrointestinal side effects. Therefore, patients with a history of gastrointestinal disease should be monitored for symptoms that may indicate an increased risk of gastrointestinal complications.

Use in Patients with History of Diabetes Mellitus

Aripiprazole, in common with other antipsychotic drugs, may cause or exacerbate diabetes mellitus. The safety and efficacy of aripiprazole in patients with a history of diabetes mellitus have not been established. Therefore, patients with a history of diabetes mellitus should be monitored for signs and symptoms of hyperglycemia or worsening of pre-existing hyperglycemia. Aripiprazole should be used with caution in patients with a history of diabetes mellitus.

Use in Patients with Liver Disease

Aripiprazole is metabolized primarily in the liver and excreted through the kidneys. In patients with liver disease, the clearance of aripiprazole is reduced. Therefore, the dose of aripiprazole should be reduced in patients with moderate to severe liver impairment. The safety and efficacy of aripiprazole in patients with severe liver impairment (Child-Pugh class C) have not been established. Use in these patients should be cautious.

Use in Patients with Renal Disease

Aripiprazole is metabolized primarily in the liver and excreted through the kidneys. In patients with renal disease, the clearance of aripiprazole is reduced. Therefore, the dose of aripiprazole should be reduced in patients with moderate to severe renal impairment. The safety and efficacy of aripiprazole in patients with severe renal impairment (creatinine clearance <30 mL/min) have not been established. Use in these patients should be cautious.

Use in Elderly Patients

Aripiprazole has not been studied in patients aged 65 years and older. Therefore, the use of aripiprazole in patients aged 65 years and older should be cautious. The dosage of aripiprazole should be reduced in patients aged 65 years and older, unless it can be demonstrated that the benefits of aripiprazole outweigh the risks in these patients.

Use in Patients with Seizure Disorders

Aripiprazole is an antipsychotic drug and may cause or exacerbate seizures. Therefore, patients with a history of seizure disorder should be monitored for signs and symptoms of a seizure.

Use in Patients with History of Substance Abuse

Aripiprazole is an antipsychotic drug and may cause or exacerbate alcohol or drug abuse. Therefore, patients with a history of substance abuse should be monitored for signs and symptoms of alcohol or drug abuse.

Use in Patients with History of Psychosis

Aripiprazole is an antipsychotic drug and may cause or exacerbate psychosis. Therefore, patients with a history of psychosis should be monitored for signs and symptoms of psychosis.

Use in Patients with History of Bipolar Disorder

Aripiprazole is an antipsychotic drug and may cause or exacerbate bipolar disorder. Therefore, patients with a history of bipolar disorder should be monitored for signs and symptoms of bipolar disorder.

Use in Patients with History of Mental Retardation

Aripiprazole is an antipsychotic drug and may cause or exacerbate mental retardation. Therefore, patients with a history of mental retardation should be monitored for signs and symptoms of mental retardation.

Use in Pregnant Women

Aripiprazole is an antipsychotic drug and may cause or exacerbate pregnancy-related complications. Therefore, pregnant women who are not already taking antipsychotic medication should be monitored for signs and symptoms of pregnancy-related complications.

Use in Nursing Women

Aripiprazole is an antipsychotic drug and may cause or exacerbate milk production. Therefore, nursing women who are not already taking antipsychotic medication should be monitored for signs and symptoms of milk production.

Use in Children and Adolescents

Aripiprazole is an antipsychotic drug and may cause or exacerbate growth suppression. Therefore, children and adolescents who are not already taking antipsychotic medication should be monitored for signs and symptoms of growth suppression.

Use in Patients with Renal Impairment

Aripiprazole is an antipsychotic drug and may cause or exacerbate renal impairment. Therefore, patients with renal impairment who are not already taking antipsychotic medication should be monitored for signs and symptoms of renal impairment.

Use in Patients with Hepatic Impairment

Aripiprazole is an antipsychotic drug and may cause or exacerbate hepatic impairment. Therefore, patients with hepatic impairment who are not already taking antipsychotic medication should be monitored for signs and symptoms of hepatic impairment.

Use in Patients with Gastrointestinal Impairment

Aripiprazole is an antipsychotic drug and may cause or exacerbate gastrointestinal impairment. Therefore, patients with gastrointestinal impairment who are not already taking antipsychotic medication should be monitored for signs and symptoms of gastrointestinal impairment.

Use in Geriatric Patients

Aripiprazole is an antipsychotic drug and may cause or exacerbate geriatric syndrome. Therefore, geriatric patients who are not already taking antipsychotic medication should be monitored for signs and symptoms of geriatric syndrome.
Aripiprazole has been evaluated for safety in 7951 patients who participated in multiple-dose, premarketing trials in patients with schizophrenia,

ADVERSE REACTIONS

weight gain for aripiprazole and placebo patients was 0.0 kg vs. -0.2 kg, respectively. The proportion of patients meeting a weight gain criterion of >7% of body weight was aripiprazole (3%) compared to placebo (2%). Table 2 provides the incidence of

ADVERSE REACTIONS

Table 2 provides the incidence of adverse events in short-term, placebo-controlled trials of patients with schizophrenia in the placbo group, the difference between placebo and aripiprazole is shown in Table 2. Other adverse events are included in the following categories: gastrointestinal effects, such as vomiting, diarrhea, constipation, and dyspepsia; respiratory effects, such as coughing, pharyngitis, rhinitis, and sinusitis; cardiovascular effects, such as edema, hypertension; and nervous system effects, such as headache, asthenia, accidental injury, and dizziness.

ADVERSE REACTIONS

Table 2. Weight Change Results Categorized by BMI at Baseline: Placebo-Controlled Study in Schizophrenia, Safety Sample

<table>
<thead>
<tr>
<th>BMI</th>
<th>Placebo-Controlled Study in Schizophrenia, Safety Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>Mean change from baseline (kg)</td>
</tr>
<tr>
<td>----</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>18</td>
<td>-0.5</td>
</tr>
<tr>
<td>22</td>
<td>-0.8</td>
</tr>
<tr>
<td>27</td>
<td>-1.3</td>
</tr>
<tr>
<td>BMI</td>
<td>2.1</td>
</tr>
</tbody>
</table>

Table 3. Weight Change Results Categorized by BMI at Baseline: Active-Controlled Study in Schizophrenia, Safety Sample

<table>
<thead>
<tr>
<th>BMI</th>
<th>Placebo-Controlled Study in Schizophrenia, Safety Sample</th>
</tr>
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<tbody>
<tr>
<td>----</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>18</td>
<td>-0.5</td>
</tr>
<tr>
<td>22</td>
<td>-0.8</td>
</tr>
<tr>
<td>27</td>
<td>-1.3</td>
</tr>
<tr>
<td>BMI</td>
<td>2.1</td>
</tr>
</tbody>
</table>

Table 3 provides the weight change results from a long-term (26-week) study of aripiprazole, both mean change from baseline and proportions of patients meeting a weight gain criterion of ≥7% of body weight relative to baseline, categorized by BMI at the start of the study.