HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ABILIFY safely and effectively. See full prescribing information for ABILIFY.

ABILIFY® (aripiprazole) Tablets
ABILIFY® DISCMELT™ (aripiprazole) Orally Disintegrating Tablets
ABILIFY® (aripiprazole) Oral Solution
ABILIFY® (aripiprazole) Injection FOR INTRAMUSCULAR USE ONLY

Initial U.S. Approval: 2002

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 atypical antipsychotic drugs are at an increased risk of death compared to placebo. ABILIFY is not approved for the treatment of patients with dementia-related psychosis. (5.1)

----------RECENT MAJOR CHANGES----------

Indications and Usage, Pediatric (13 to 17 yrs) Schizophrenia (1.1)	10/2007
Dosage and Administration, Pediatric Schizophrenia (2.1)	10/2007

----------INDICATIONS AND USAGE----------

ABILIFY is an atypical antipsychotic indicated
as oral formulations for:

- Treatment of Schizophrenia in adults and adolescents aged 13-17 years (1.1)
- Treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults (1.2)

as an injection for:

- Treatment of adults with agitation associated with Schizophrenia or Bipolar I Disorder, manic or mixed (1.3)

----------DOSAGE AND ADMINISTRATION----------

	Initial Dose	Recommended Dose	Maximum Dose
Schizophrenia-adults (2.1)	10-15 mg /day	10-15 mg /day	30 mg /day
Schizophrenia – adolescents (2.1)	2 mg /day	10 mg /day	30 mg /day
Bipolar Mania– adults (2.2)	15-30 mg /day	15-30 mg /day	30 mg /day
Agitation associated with Schizophrenia or Bipolar Mania– adults (2.5)	9.75 mg /1.3 mL injected IM		30 mg /day injected IM

- ABILIFY oral formulations: Administer once daily without regard to meals (2)
- ABILIFY injection: Wait at least 2 hours between doses. Maximum daily dose 30 mg (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

- Tablets: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg (3)
- Orally Disintegrating Tablets: 10 mg and 15 mg (3)
- Oral Solution: 1 mg/mL (3)
- Injection: 9.75 mg/1.3 mL single-dose vial (3)

----------CONTRAINDICATIONS----------

Known hypersensitivity to ABILIFY (4)

----------WARNINGS AND PRECAUTIONS----------

- *Elderly patients with dementia-related psychosis:* Increased incidence of cerebrovascular adverse events (eg, stroke, transient ischemic attack, including fatalities) (5.1)
- *Neuroleptic Malignant Syndrome*: Manage with immediate discontinuation and close monitoring (5.2)
- *Tardive Dyskinesia:* Discontinue if clinically appropriate (5.3)
- *Hyperglycemia and Diabetes Mellitus*: Monitor glucose regularly in patients with and at risk for diabetes (5.4)
- *Orthostatic Hypotension:* Use with caution in patients with known cardiovascular or cerebrovascular disease (5.5)
- *Seizures/Convulsions:* Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold (5.6)
- *Potential for Cognitive and Motor Impairment:* Use caution when operating machinery (5.7)
- *Suicide:* Closely supervise high-risk patients (5.10)

----------ADVERSE REACTIONS----------

Commonly observed adverse reactions (incidence ≥ 5%and at least twice that for placebo) were (6.2):

- Adult patients with Schizophrenia: akathisia
- Pediatric patients (13 to 17 yrs) with Schizophrenia: extrapyramidal disorder, somnolence, and tremor
- Adult patients with Bipolar Mania: constipation, akathisia, sedation, tremor, restlessness, and extrapyramidal disorder
- Adult patients with agitation associated with Schizophrenia or Bipolar Mania: nausea .

To report SUSPECTED ADVERSE REACTIONS, contact Bristol-Myers Squibb at 1-800-721-5072 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

----------DRUG INTERACTIONS----------

- *Strong CYP3A4 or CYP2D6 inhibitors will increase* ABILIFY drug concentrations; reduce ABILIFY dose by one-half when used concomitantly (2.1, 7.1)
- *CYP3A4 inducers will decrease* ABILIFY drug concentrations; double ABILIFY dose when used concomitantly (2.1, 7.1)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 10/2007

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 atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen 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 (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. ABILIFY (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis. *[see WARNINGS AND PRECAUTIONS (5.1)].*

1 INDICATIONS AND USAGE

1.1 Schizophrenia

Adults

ABILIFY is indicated for acute and maintenance treatment of Schizophrenia *[see CLINICAL STUDIES (14.1)]*.

Adolescents

ABILIFY is indicated for the treatment of Schizophrenia in adolescents 13 to 17 years of age *[see CLINICAL STUDIES (14.1)]*.

1.2 Bipolar Disorder

Adults

ABILIFY is indicated for acute and maintenance treatment of manic and mixed episodes associated with Bipolar I Disorder with or without psychotic features *[see CLINICAL STUDIES (14.2)]*.

1.3 Agitation Associated with Schizophrenia or Bipolar Mania

Adults

ABILIFY Injection is indicated for the treatment of agitation associated with Schizophrenia or Bipolar Disorder, manic or mixed. "Psychomotor agitation" is defined in DSM-IV as "excessive motor activity associated with a feeling of inner tension." Patients experiencing agitation often manifest behaviors that interfere with their diagnosis and care (eg, threatening behaviors, escalating or urgently distressing behavior, or self-exhausting behavior), leading clinicians to the use of intramuscular antipsychotic medications to achieve immediate control of the *agitation [see CLINICAL STUDIES (14.3)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Schizophrenia

Usual Dose

Adults

The recommended starting and target dose for ABILIFY is 10 mg/day or 15 mg/day administered on a once-a-day schedule without regard to meals. ABILIFY has been systematically evaluated and shown to be effective in a dose range of 10 mg/day to 30 mg/day, when administered as the tablet formulation; however, doses higher than 10 mg/day or 15 mg/day were not more effective than 10 mg/day or 15 mg/day. Dosage increases should not be made before 2 weeks, the time needed to achieve steady state. *[See CLINICAL STUDIES (14.1)]*.

Adolescents

The recommended target dose of ABILIFY is 10 mg/day. Aripiprazole was studied in pediatric patients 13 to 17 years of age with Schizophrenia at daily doses of 10 mg and 30 mg. The starting daily dose of the tablet formulation in these patients was 2 mg, which was titrated to 5 mg after 2 days and to the target dose of 10 mg after 2 additional days. Subsequent dose increases should be administered in 5 mg increments. The 30 mg/day dose was not shown to be more efficacious than the 10 mg/day dose. ABILIFY can be administered without regard to meals. *[See CLINICAL STUDIES (14.1)]*.

Dosage in Special Populations

Dosage adjustments are not routinely indicated on the basis of age, gender, race, or renal or hepatic impairment status *[see USE IN SPECIFIC POPULATIONS (8.4-8.10)]*.

Dosage adjustment for patients taking aripiprazole concomitantly with strong CYP3A4 inhibitors: When concomitant administration of aripiprazole with strong CYP3A4 inhibitors such as ketoconazole or clarithromycin is indicated, the aripiprazole dose should be reduced to one-half the usual dose. When the CYP3A4 inhibitor is withdrawn from the combination therapy, the aripiprazole dose should then be increased *[see DRUG INTERACTIONS (7.1)]*.

Dosage adjustment for patients taking aripiprazole concomitantly with potential CYP2D6 inhibitors: When concomitant administration of potential CYP2D6 inhibitors such as quinidine, fluoxetine, or paroxetine with aripiprazole occurs, aripiprazole dose should be reduced at least to one-half of its normal dose. When the CYP2D6 inhibitor is withdrawn from the combination therapy, the aripiprazole dose should then be increased *[see DRUG INTERACTIONS (7.1)]*.

Dosage adjustment for patients taking potential CYP3A4 inducers: When a potential CYP3A4 inducer such as carbamazepine is added to aripiprazole therapy, the aripiprazole dose should be doubled. Additional dose increases should be based on clinical evaluation. When the CYP3A4 inducer is withdrawn from the combination therapy, the aripiprazole dose should be reduced to 10 mg to 15 mg *[see DRUG INTERACTIONS (7.1)]*.

Maintenance Therapy

Adults

While there is no body of evidence available to answer the question of how long a patient treated with aripiprazole should remain on it, systematic evaluation of patients with Schizophrenia who had been symptomatically stable on other antipsychotic medications for periods of 3 months or longer, were discontinued from those medications, and were then administered ABILIFY 15 mg/day and observed for relapse during a period of up to 26 weeks, has demonstrated a benefit of such maintenance treatment *[see CLINICAL STUDIES (14.1)]*. Patients should be periodically reassessed to determine the need for maintenance treatment.

DOCKET ALARM

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