Abilify

(aripiprazole)

Abilify (aripiprazole); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Abilify is an atypical antipsychotic approved for irritability associated with autistic disorder, Tourette's disorder, pediatric bipolar I mania, and adolescent schizophrenia. It is a partial agonist at dopamine D2 rather than a full antagonist, which gives it a lower prolactin and extrapyramidal burden than risperidone. In an ADHD practice it is reached for when aggression or severe irritability persists despite optimised stimulant therapy, not as an ADHD treatment. Not controlled; brand and generic.

Forms & Strengths

- **Tablets:** 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg
- **Orally disintegrating tablets:** 10 mg, 15 mg, 20 mg, 30 mg
- **Oral solution:** 1 mg/mL
- **Oral soluble film** (Opipza): 10 mg
- **Long-acting injectables** (Abilify Maintena, Aristada, Asimtufii): separate products with their own labels

Dosing

- **Age:**
  - Irritability with autistic disorder: 6-17 y/o
  - Tourette's disorder: 6-18 y/o
  - Bipolar I, acute mania or mixed: 10-17 y/o
  - Schizophrenia: 13-17 y/o

- **Onset:** 1-2 weeks for behavioural effect; steady state within 14 days
- **Duration:** continuous with once-daily dosing
- **Initial Dose:** 2 mg once daily for every pediatric indication
- **Titration:** increase at intervals of no less than 1 week; target 5-10 mg/day for autism irritability, 10 mg/day for bipolar I and schizophrenia
- **Max Dose:**
  - Irritability with autistic disorder: 15 mg/day
  - Tourette's, under 50 kg: 10 mg/day
  - Tourette's, 50 kg and over: 20 mg/day
  - Bipolar I: 30 mg/day
  - Schizophrenia: 30 mg/day
- **Considerations:** May be taken with or without food. Halve the usual dose in CYP2D6 poor metabolizers and with strong CYP2D6 or CYP3A4 inhibitors. Tourette's dosing bands by weight, not age.

Pharmacology

- **Mechanism:** Partial agonist at D2 and 5-HT1A, antagonist at 5-HT2A
- **Class Positioning:** D2 partial agonism gives a lower prolactin and EPS burden than risperidone (Risperdal); akathisia is the trade-off and the commonest reason for discontinuation
- **Metabolism:** CYP2D6 and CYP3A4, to the active metabolite dehydro-aripiprazole
- **Half-life:** about 75 hours for aripiprazole, 94 hours for dehydro-aripiprazole, about 146 hours in CYP2D6 poor metabolizers
- **Pharmacogenomics:** CYP2D6 poor metabolizers receive half the usual dose; this is a labeled adjustment, not advisory

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Indications

- **Irritability Associated with Autistic Disorder** (ICD-10: F84.0): patients 6-17 y/o
- **Tourette's Disorder** (ICD-10: F95.2): patients 6-18 y/o
- **Bipolar I Disorder, acute mania or mixed episodes** (ICD-10: F31.x): patients 10-17 y/o and adults
- **Schizophrenia** (ICD-10: F20.x): patients 13-17 y/o and adults
- **Major Depressive Disorder, adjunctive** (ICD-10: F32.x, F33.x): adults only

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Off-Label Uses

- **Severe aggression and disruptive behaviour** (ICD-10: F90.x, F91.x): second line, after behavioural intervention and optimised treatment of the primary disorder. Evidence for aripiprazole graded insufficient to low; expert consensus. (AACAP 2011; AHRQ 2017)
- **Anxiety disorders** (ICD-10: F41.x): insufficient; no eligible pediatric studies were identified at all. (AHRQ 2017)
- **Obsessive-compulsive disorder** (ICD-10: F42.x): insufficient; the effect of aripiprazole augmentation is not known. (AHRQ 2017)
- **Depression** (ICD-10: F32.x, F33.x): insufficient in youth. The adult adjunctive MDD indication does not extend to children. (AHRQ 2017)

Contraindications & Warnings

- **Boxed Warning:** Increased mortality in elderly patients with dementia-related psychosis; aripiprazole is not approved for that use. Also suicidal thoughts and behaviors when used with antidepressants: screen at every visit.
- **Contraindicated:**
  - Known hypersensitivity to aripiprazole or any component of the formulation.
- **Use with caution:**
  - Cardiovascular or cerebrovascular disease, or any condition predisposing to hypotension.
  - Diabetes, obesity, or a family history of either.
  - Seizure history or a lowered seizure threshold.
  - Conditions raising core temperature: strenuous exercise, heat exposure, anticholinergic co-medication.
- **Screen before starting:**
  - Weight, BMI, and waist circumference.
  - Fasting glucose or A1c, and a fasting lipid panel.
  - Personal and family history of diabetes, dyslipidemia, and cardiovascular disease.
  - Baseline abnormal involuntary movements, using AIMS.

Drug Interactions

- **Strong CYP2D6 or CYP3A4 inhibitors** (fluoxetine, paroxetine, quinidine, ketoconazole, itraconazole, clarithromycin): give half the usual dose.
- **Both a strong CYP2D6 and a strong CYP3A4 inhibitor:** give a quarter of the usual dose.
- **CYP2D6 poor metabolizer on a strong CYP3A4 inhibitor:** give a quarter of the usual dose.
- **Strong CYP3A4 inducers** (carbamazepine, rifampin): double the usual dose over 1 to 2 weeks; reverse when the inducer stops.

- **Antihypertensives:** additive hypotension; check orthostatic vitals after any dose change.
- **CNS depressants and alcohol:** additive sedation; counsel explicitly in adolescents.

Administration

- Give once daily, at the same time each day, with or without food.
- **Tablet:** swallow whole.
- **Orally disintegrating tablet:** place on the tongue and let it dissolve; do not chew, crush, or push through the foil.
- **Oral solution:** measure with a dosing syringe or calibrated cup; at 1 mg/mL doses map directly to millilitres.
- If a dose is missed, give it unless the next dose is near; do not double up.
- Do not stop abruptly. See Discontinuation & Taper.

Side Effects

- **Common:** akathisia and restlessness, sedation and fatigue, weight gain, nausea and vomiting, headache, dizziness, constipation, insomnia
- **Serious:**
  - Tardive dyskinesia: assess with AIMS; discontinue where clinically possible if it emerges.
  - Neuroleptic malignant syndrome: fever, rigidity, altered mental status, autonomic instability. Treat as an emergency.
  - Hyperglycemia and new-onset diabetes, including ketoacidosis: check glucose for polyuria, polydipsia, or unexplained weight loss.
  - Orthostatic hypotension and syncope: check lying and standing blood pressure at each dose change.
  - Seizures.
  - Leukopenia, neutropenia, agranulocytosis: check CBC with fever or infection; discontinue if ANC falls below 1000/mm3.
  - Pathological gambling, binge eating, compulsive shopping, hypersexuality: ask directly, since patients rarely volunteer them.
  - Dysphagia and laryngeal or dystonic reactions.

Monitoring & Labs

- **Weight and BMI:** at 4, 8, and 12 weeks after starting or changing dose, then quarterly. Consider switching agent on a gain of 5% or more. (ADA 2004)

- **Fasting glucose or A1c:** at baseline and 12 weeks, then annually; sooner with weight gain, family history, or metabolic change. (ADA 2004)
- **Fasting lipids:** at baseline and 12 weeks, then every 5 years if normal; recheck when weight or glucose moves. (ADA 2004)
- **Blood pressure:** at baseline and 12 weeks, annually thereafter, plus orthostatics at every dose change. (ADA 2004)
- **Movement:** AIMS at baseline and every 3 months in children; ask about akathisia at every visit during titration.
- **Prolactin:** only if symptomatic, meaning galactorrhea, gynecomastia, amenorrhea, or delayed puberty. Aripiprazole usually lowers prolactin.
- **CBC:** not routine; check with fever, infection, or a history of leukopenia or neutropenia.

Discontinuation & Taper

- Taper gradually rather than stopping abruptly, to minimise withdrawal effects. Guideline recommendation, not a labeled instruction. (AACAP 2011)
- Reassess the continued need regularly; document indication, response, and rationale for continuing. (AACAP 2011)
- The long half-life means levels fall slowly, so withdrawal or rebound may appear days after the last dose.
- Discontinue immediately if neuroleptic malignant syndrome is suspected.
- Discontinue for severe neutropenia, an absolute neutrophil count below 1,000/mm3.

Pregnancy & Lactation

- **Pregnancy:** Third-trimester exposure may cause neonatal extrapyramidal or withdrawal symptoms. Weigh continued treatment against relapse of the maternal condition rather than stopping reflexively.
- **Lactation:** Maternal doses up to 15 mg daily give low milk levels; relative infant dose ranges from under 0.7% to 12.7%. Monitor for dehydration and inadequate weight gain. (LactMed 2026)
- **Milk supply:** Aripiprazole lowers prolactin dose-dependently and can suppress lactation outright. Raise this before starting in a patient who intends to breastfeed. (LactMed 2026)
- **Exposure Registry:** National Pregnancy Registry for Atypical Antipsychotics, 1-866-961-2388, womensmentalhealth.org.

Counseling Points

- **Counsel the family on:**

    - Restlessness in the first weeks. Name akathisia explicitly; families read it as worsening behaviour and stop the drug.
    - Appetite increase and weight gain, and that weight is plotted at every visit.
    - Effect on irritability building over 1-2 weeks, so the first week is not a fair trial.
    - Rising slowly from lying or sitting during titration.
    - Extra caution with heat and strenuous exercise; the drug impairs temperature regulation.
    - Never stopping abruptly, even if the medication seems to be doing nothing.
- **Advise them to call for:**
    - Fever with muscle stiffness or confusion, which is an emergency.
    - Any involuntary movement of the face, tongue, or limbs.
    - Fainting, or dizziness on standing that does not settle.
    - Marked thirst, frequent urination, or unexplained weight loss.
    - New gambling, spending, eating, or sexual urges that feel out of character.
    - New or worsening suicidal thoughts, especially alongside an antidepressant.

References

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