

Abilify Asimtufii[®] (aripiprazole) – New drug approval

- On April 28, 2023, [Otsuka and Lundbeck announced](#) the FDA approval of [Abilify Asimtufii \(aripiprazole\)](#) extended-release injectable suspension, for the treatment of schizophrenia in adults and for maintenance monotherapy treatment of bipolar I disorder in adults.
- Aripiprazole is available in other formulations, including injectable [Aristida[®]](#) and [Abilify Maintena[®]](#).
 - Abilify Maintena shares the same indications as Abilify Asimtufii.
 - Aristada is approved for the treatment of schizophrenia in adults.
- The efficacy of Abilify Asimtufii (once every 2-month dosing) was based on adequate and well-controlled studies of Abilify Maintena (once monthly dosing).
- Abilify Asimtufii carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.
- Additional warnings and precautions for Abilify Asimtufii include cerebrovascular adverse reactions, including stroke in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; pathological gambling and other compulsive behaviors; orthostatic hypotension and syncope; falls; leukopenia, neutropenia, and agranulocytosis; seizures; potential for cognitive and motor impairment; body temperature regulation; and dysphagia.
- The most common adverse reactions (≥ 5% and at least twice the rate of placebo) with Abilify Asimtufii use were increased weight, akathisia, injection site pain, and sedation.
- The recommended dose of Abilify Asimtufii is 960 mg, administered once every 2 months (56 days after previous injection).
 - For patients who have never taken aripiprazole, tolerability should be established with oral aripiprazole prior to initiating treatment with Abilify Asimtufii. Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability.
 - Abilify Asimtufii must be administered as an intramuscular gluteal injection by a healthcare professional.
 - Refer to the Abilify Asimtufii drug label for complete dosing and administration recommendations.
- Lundbeck's launch plans for Abilify Asimtufii are pending. Abilify Asimtufii will be available as 960 mg/3.2 mL and 720 mg/2.4 mL single-dose pre-filled syringes.