



## Aristada® (aripiprazole lauroxil) – New formulation approval

- On June 6, 2017, [Alkermes announced](#) the FDA approval of two-month [Aristada \(aripiprazole lauroxil\)](#) extended-release injectable suspension, for the treatment of schizophrenia.
- Previously, Aristada was available for administration once monthly to once every 6 weeks.
- The efficacy of Aristada's two-month injection was established by pharmacokinetic bridging, which demonstrated that the dosing regimen resulted in plasma aripiprazole concentrations that are within the range provided by the lower doses of Aristada once monthly injections.
- Similar to other antipsychotics, Aristada carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.
- Aristada can be initiated at a dose of 441 mg, 662 mg, or 882 mg by intramuscular (IM) injection once monthly, 882 mg every 6 weeks, or 1,064 mg every 2-months.
  - IM administration should be given in the deltoid (441 mg only) or gluteal muscle (441 mg, 662 mg, 882 mg, or 1,064 mg) by a healthcare professional.
  - For patients who are naïve to aripiprazole, healthcare providers should establish tolerability with oral aripiprazole prior to initiating treatment with Aristada.
  - In conjunction with the first Aristada injection, patients should receive treatment with oral aripiprazole for 21 consecutive days.
- Alkermes plans to launch the new two-month Aristada 1,064 mg injectable suspension in mid-June.



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