# Use of an Aripiprazole Lauroxil Injection Administered Once Every Month, 6 Weeks, or 2 Months in People With Schizophrenia: A Clinician-Focused Summary of Study Data

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## INTRODUCTION

**Long-acting injectable (LAI) antipsychotic medications have the potential to:**

- Assure clinicians that patients are continuing their medication[1]
- Support tolerability with stable medication levels[1,2]
- Enhance adherence, which may reduce risk of relapse and hospitalization[1,3,4]
- Support patients through the transition from inpatient to outpatient care[5]

- **Aripiprazole lauroxil** is an LAI form of the antipsychotic aripiprazole for adults with schizophrenia[6]
- Here we present a clinician-focused summary of key findings from published articles about aripiprazole lauroxil, including treatment aripiprazole lauroxil and dosing options, effects on symptoms of schizophrenia, and side effects reported in study participants

## DEVELOPMENT OF THE LAI ARIPIPRAZOLE LAUROXIL

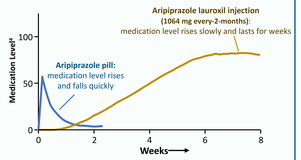
### Aripiprazole lauroxil was designed to provide long-lasting and steady medication levels

**Each injection provides long-lasting medication**

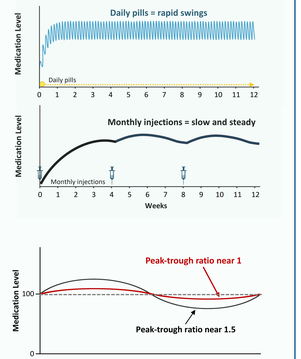
- Aripiprazole lauroxil is a "prodrug," or an inactive form of aripiprazole that is activated after injection[7]
- This prodrug forms crystals that dissolve slowly[8]
- When patients are given an aripiprazole lauroxil injection, the prodrug releases medication over weeks (compared with days for an aripiprazole pill)[7]
- As a result, aripiprazole lauroxil can provide long-lasting levels of aripiprazole[8]

**Medication levels remain steady between injections**

- Increasing the time between doses means fewer shots; longer dosing intervals are possible if medication levels remain steady between injections
- The rise and fall of medication levels between doses is described by a "peak-trough ratio" or PTR[2]
- If there was no variability, the PTR would be 1
- The PTR for once-monthly aripiprazole lauroxil[b] is very close to 1[9]
- The PTR for an aripiprazole LAI that does not use a prodrug is closer to 1.5[1]




**Medication level illustrations**

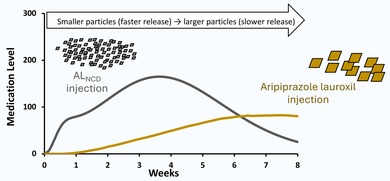



[a]Aripiprazole pill: observed data; aripiprazole lauroxil: model-simulated values. [b]Estimated from drug levels collected in clinical trials.[6]

## INITIATION AND DOSING OPTIONS

### Aripiprazole lauroxil treatment can be initiated in a single day

- Medication levels rise slowly when starting an LAI, so it takes time for the drug to reach levels needed to treat symptoms[8]
- Treatment can be started with an aripiprazole lauroxil initiation formulation, or **$AL_{NCD}$**, with a single 30-mg aripiprazole pill to quickly increase medication levels with the first aripiprazole lauroxil dose[a]
- Alternatively, patients need daily aripiprazole pills for 3 weeks after the first aripiprazole lauroxil injection so that they have enough medication right away
- $AL_{NCD}$ crystals are smaller, dissolve faster than aripiprazole lauroxil crystals, and increase drug levels more rapidly[8]

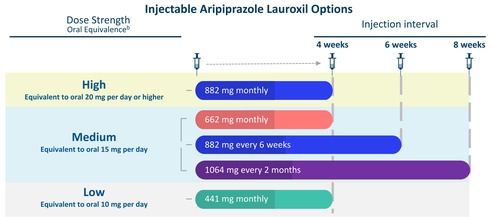



- Aripiprazole lauroxil treatment can be started with a 1-day regimen[b] ($AL_{NCD}$ plus a single aripiprazole pill) instead of 21 daily pills[6]


[a]$AL_{NCD}$ can be administered on the same day as aripiprazole lauroxil or up to 10 days thereafter. [b]The 1-day regimen can be used with any dose strength. Tolerability must be established with oral aripiprazole before initiating treatment with $AL_{NCD}$.
$AL_{NCD}$, aripiprazole lauroxil NanoCrystal Dispersion formulation.

### Aripiprazole lauroxil injections are available in multiple dosing options to fit different patients' treatment needs

- All options provide[a] medication levels within the same ranges as aripiprazole pills




[a]Aripiprazole lauroxil can be given monthly, every 6 weeks, or every 2 months and can be prescribed at a low, medium, or high dose
[b]Total daily doses for patients who are stabilized on oral aripiprazole and the recommended intramuscular aripiprazole lauroxil dose.

## TREATMENT OF SYMPTOMS

### Aripiprazole lauroxil injections have been assessed in clinical studies looking at acute, maintenance, and long-term treatment up to 3½ years

| Study | Design | Reference |
|---|---|---|
| **Pivotal study** | 3-month efficacy and safety of aripiprazole lauroxil monthly versus placebo in adults with acute schizophrenia | Meltzer et al (2015)[10] |
| **Safety study** | 1-year safety of aripiprazole lauroxil monthly in adults with stable schizophrenia | Nasrallah et al (2019)[11] |
| **ALPINE study** | 1-month and 6-month efficacy and safety of aripiprazole lauroxil every-2-months in adults hospitalized for acute schizophrenia | Weiden et al (2020)[5] |
| **Extension study** | 1- to 2½-year safety of aripiprazole lauroxil monthly in adults who already had 1 year of study treatment | Lauriello et al (2020)[12] |

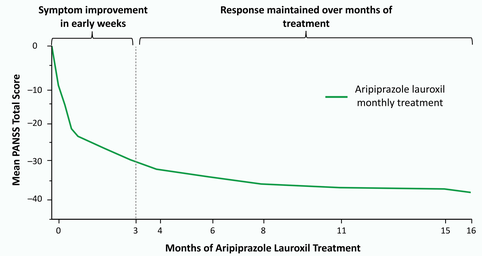
### Aripiprazole lauroxil injections reduce acute symptoms of schizophrenia

**Aripiprazole lauroxil monthly injections reduced symptoms of schizophrenia in the pivotal study[10]**

**Aripiprazole lauroxil every-2-months injections reduced symptoms of schizophrenia in the ALPINE study[5]**

- Aripiprazole lauroxil reduced symptom severity similarly in men and women and in older and younger adults[13]
- Symptoms improved with aripiprazole lauroxil treatment, regardless of how severe patients' symptoms were when they started treatment[14]
  - Patients with more severe symptoms[a] had greater improvement

### Aripiprazole lauroxil injections maintain improvements over time[15]

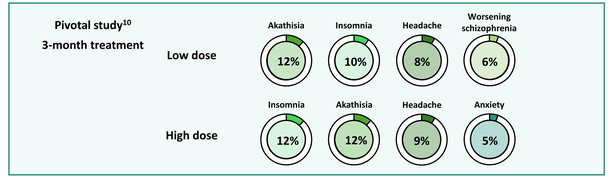


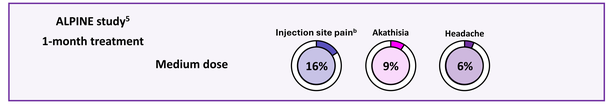

[a]Severe symptoms defined as a Clinical Global Impression–Severity score of 6 or higher.
PANSS, Positive and Negative Syndrome Scale.

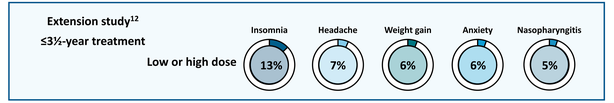
## SAFETY AND TOLERABILITY

### Aripiprazole lauroxil injections are safe for acute and long-term treatment

Side effects reported by 5% or more of study patients who received aripiprazole lauroxil injections[a]:




[a]For the full safety profile, including complete list of adverse effects and reasons for discontinuation, for each dosing regimen in the clinical trials, see references 5, 10, and 12.
[b]The ALPINE study included placebo injections, which contributed to reports of injection site pain.

## CONCLUSIONS

- **Aripiprazole lauroxil's prodrug design provides steady, long-lasting medication levels**
- **Using the 1-day initiation regimen, aripiprazole lauroxil can be started in a single day, supporting a transition to ongoing treatment without the need for additional pills**
- **Aripiprazole lauroxil is available in several doses and injection schedules to tailor treatment to individual patient treatment needs and preferences**
- **Aripiprazole lauroxil injections are a safe and effective treatment for acute and long-term schizophrenia care[16]**

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## DISCLOSURES

**BK** has been on an advisory board for Alkermes, Axsome, BMS, Indivior, Intra-Cellular Therapies, Janssen, Johnson & Johnson, Neurocrine, Otsuka, Takeda, and Teva and is on the speakers' bureau for AbbVie, Alkermes, Axsome, BMS, Intra-Cellular Therapies, Janssen, Johnson & Johnson, Luye, Otsuka, Sage, Takeda, and Teva. **JAC** has been a consultant and/or on an advisory board for Alkermes, Bristol Myers Squibb, Otsuka, and Supernus. **RB** has been a consultant or on an advisory board for AbbVie, Alkermes, Axsome Therapeutics, Neurocrine Biosciences, and Tempus and is on the speakers' bureau for Alkermes, Axsome Therapeutics, Intra-Cellular Therapies, Neurocrine, and Tempus. **AJC** has been a consultant or on an advisory board for AbbVie, Acadia, Alfasigma, Alkermes, Anavex Life Sciences, Autobahn Therapeutics, Axsome, Biogen, Biohaven, BioXcel, Boehringer Ingelheim, Bristol Myers Squibb, Cerevel, Collegium Pharmaceutical, Corium, Delpor, 4M Therapeutics, Intra-Cellular Therapies, Johnson & Johnson Innovative Medicine, Jazz Pharma, Karuna, Knight Therapeutics, LivaNova, Lundbeck, Luye Pharma, MapLight Therapeutics, Mentavi, Neumora, Neurocrine, NeuroSigma, Noven, Otsuka, PaxMedica, Relmada, Sage Therapeutics, Supernus, Teva, Thynk, Tris Pharma, Vanda Pharmaceuticals, and VistaGen; is on the speakers' bureau for AbbVie, Alfasigma, Alkermes, Axsome, Boehringer Ingelheim, Bristol Myers Squibb, Collegium Pharmaceutical, Corium, Innovative Medicine, Intra-Cellular Therapies, Johnson & Johnson, Knight Therapeutics, Lundbeck, Neurocrine, Noven, Otsuka, Supernus, Teva, Tris Pharma, and Vanda Pharmaceuticals; is on a data safety monitoring board for COMPASS Pathways; holds stock options from 4M Therapeutics; and receives no royalties. **CC** has been a consultant and/or on an advisory board for AbbVie, Acadia, Alkermes, Axsome, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Corium, Eli Lilly, Idorsia, Intra-Cellular, Jazz, Johnson & Johnson, Lundbeck, MedinCell, Moderna, Neurocrine, Otsuka, Sage, Sumitomo, Supernus, Takeda, and Teva; has received grant or research support from Acadia, Axsome, Harmony, Neurocrine, and Teva; is on the speakers' bureau for AbbVie, Acadia, Alkermes, Axsome, Bristol Myers Squibb, Corium, Intra-Cellular, Jazz, Johnson & Johnson, Lundbeck, Luye, Merck, Neurocrine, Otsuka, Sumitomo, Takeda, and Teva; and has no stocks, stock options, ownership interests, or patents. **MST**, **DJK**, **JAM**, and **DM** are employees of Alkermes, Inc., and may own stock/options in the company. **PJW** is a former employee of Alkermes, Inc.; has been a consultant for AbbVie, Alkermes, Anavex, Boehringer-Ingelheim, Bristol Myers Squibb, Delpor, Luye, MapLight Therapeutics, Serina Therapeutics, Teva, and Vanda; is on the speakers' bureau for Alkermes, Bristol Myers Squibb, Luye, Neurocrine, and Vanda; and has stock options in Delpor.

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